Edinburgh Community Healthcare Partnership

Chalmers Sexual Health Centre
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www.lothiansexualhealth.scot.nhs.uk

NHS Lothian

PARTICIPANT INFORMATION SHEET AND INFORMED CONSENT FORM
(INCLUDES PRIVACY NOTICE)

A Phase 3, Open-Label, Multicentre Study to Evaluate Contraceptive Efficacy and Safety of Depot Medroxyprogesterone Acetate (150 mg/mL) Injected Subcutaneously Every Six Months

Short title: "DMPA XT"

FHI 360 Study Number: 1706176

Version 5.0

Study Sponsor: FHI 360

Study Investigator: Professor Sharon Cameron

Site No. 005

Site Name and Address: Chalmers Centre

2a Chalmers Street, Edinburgh EH3 9ES
0131 536 1070 or 0131 536 1010

Participant Study Number: ___ ___ ___ ___

Participant Name: _____

Important information about taking part in this research study

A person who takes part in a research study is called a participant. In this consent form, "you" always refers to the participant.

You are being asked to take part in a research study because you are a healthy female between the ages of 18-35 years old who does not plan to become pregnant for at least 12 months. Taking part in this research study is voluntary. You don't have to participate, and you can stop at any time.

Please take time to read this entire form and ask questions before deciding whether you want to take part in this research study.

The purpose of this research is to see if the contraceptive injection containing depot medroxyprogesterone acetate (DMPA) that is currently given every 3 months is as effective and safe if given every 6 months under the skin instead of into the muscle. As part of this research study, we plan to enrol a total of up to 750 participants. Before you join the study, we will perform a physical and gynaecological examination and test your blood for anaemia to make sure you are in good health to be in the study. If you can and choose to participate, you will receive two contraceptive injections 6 months apart. After your first injection, you will be asked to visit the clinic at least 4 more times. Your time spent in the study will last approximately 13 months. At each of these visits we will measure your body weight, blood pressure, and give you a pregnancy test. We will ask you questions about your health, medications, any bleeding and how you feel about this method of contraception. At three of the clinic visits, we will draw a small sample of blood from your arm to test hormone levels. During each of the study visits when you will have blood collected, there is only

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one blood draw (needle into arm) to collect all blood samples. We will ask you to take monthly urine pregnancy tests at home while in the study.

We estimate the risk of unintended pregnancy in this study to be low but it is unknown so there is a chance you may become pregnant during the study. Additional risks include but not limited, to irregular bleeding, a skin reaction at the injection site and delayed return of ability to become pregnant after you stop using the method.

If you are interested in learning more about this study, please continue reading below.

Introduction

This consent form gives you information to help you decide if you want to participate in the research study named above. This consent form may contain some words that are not familiar to you. Please ask us to explain anything you do not understand. You will also have a chance to ask questions at any time. If you decide to participate, we will ask you to sign this form and we will offer to give you a signed copy of this form.

Why are we doing this study?

We are doing this study to find out if the existing 3-month contraceptive injection containing depot medroxyprogesterone acetate (DMPA) is effective and safe for 6 months when given under the skin instead of into the muscle. A previous study of 21 women has shown that DMPA stopped 21 women from ovulating (i.e., releasing eggs) for at least 6 months when it was given under the skin. In this study we will test if it prevents actual pregnancy and is safe among a larger number of women.

General information about the study

DMPA is a 3-month contraceptive injection known under different brand names (e.g., Depo Provera). In this study we will test a similar preparation of the medication called TRICLOFEM®, but instead of injecting it into the muscle, we will inject it under the skin (subcutaneously or SC). Because we are changing the way we give this drug in this study, we will use a different name and call it “6-month DMPA SC”.

Please remember that this study is research. It is not medical treatment. We are studying TRICLOFEM injected under the skin to evaluate how well it works at preventing pregnancy for 6 months and its safety. There is no guarantee that the study drug will prevent pregnancy.

The study will enrol up to 750 healthy people at risk of becoming pregnant that are 18 to 35 years old across four countries. Approximately 200 people will participate in this study in the United Kingdom. All individuals participating in the study will be randomly assigned (like flipping a coin) to receive an injection of 6-month DMPA SC under the skin of either the abdomen or upper thigh.

A description of this clinical trial will be available on the internet at the following websites: https://www.isrctn.com/ (United Kingdom) or https://sanctr.samrc.ac.za/ (South Africa). These websites will not include information that can identify you. At most, the websites will include a summary of the study results. You can search these websites at any time.

What will happen if I take part in this study?

If you participate in this study, you will receive two injections of 6-month DMPA SC under the skin of your abdomen or thigh from the study nurse: the first one on the day of enrolment, and the second

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one 6 months later. You will be in the study for approximately 13 months (including the screening visit). During the study we will ask you to return to the clinic for several different kinds of visits.

The first visit is called the Screening Visit and will last about 1 hour. No procedures can be done to you until you agree to take part in this study by signing the consent form. The procedures done at this visit will help you and the study staff determine if you are eligible to participate in this study.

Screening

During the Screening process, which may be completed today or over more than one visit we will:

- Explain the study and study procedures
- Confirm with you that you do not want to get pregnant at least over the next year
- Ask you to sign this informed consent form
- Give you a study number
- Ask you questions about your medical, sexual, and reproductive history, and health
- Record information about your typical menstrual bleeding and cramping
- Measure your vital signs, which are blood pressure and pulse, height, and weight
- Give you a general physical examination and gynaecological examinations including examining your breasts
- Collect a urine sample for a pregnancy test
- Take a blood sample from your arm to test your haemoglobin and haematocrit (about 1 teaspoon)
- Collect your contact information
- Schedule your Enrolment Visit during the first 5 days of your next period (and/or at the time of discontinuation of another contraceptive method that you are currently using)

Enrolment Visit (Day 0)

If you are eligible for the study, and agree to participate, we will ask you to return on a separate day for an Enrolment visit. Note that you may be found ineligible to participate in the study during the screening visit, or at the enrolment visit. The timing of this visit will depend on which contraceptive method you're already using, if any.

During the Enrolment visit, which will last about 1 hour, we will:

- Confirm that you are menstruating if you are not switching from another contraceptive method
- Confirm answers to some of the questions you gave during Screening about your medical history and health to make sure you still can be in the study
- Ask you about any new or worsened medical problems and if you took new drugs since your last visit
- Measure your vital signs and weight
- Collect a urine sample for a pregnancy test
- Take a blood sample (about 1 teaspoon) from your arm for possible testing for Medroxyprogesterone Acetate (MPA), the hormone that is in 6-month DMPA SC, to make sure that you don't have any MPA in your body. We will run this test only if indicated.
- Take a blood sample (about 1 teaspoon) to test your levels of estradiol and progesterone, which are natural hormones that are affected if you use the contraceptive injection
- If you agree, we will draw about 1 teaspoon more of blood to store for future testing (we will explain in the "Optional Specimen Collection" section below)
- Randomly assign (like flipping a coin) you to one of the 2 study groups (injection given in the abdomen or upper thigh)

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- After we complete the steps above, give you an injection of 6-month DMPA SC under the skin in your abdomen **or** upper thigh
- Mark and take a photo of the injection location
- Ask you to wait at least 15 minutes after your injection to make sure you do not have an allergic reaction
- Give you a diary and instructions for use throughout the study to record your vaginal bleeding, sexual activity and condom use
- Provide several urine pregnancy tests with instructions when and how to use at home
- Ask you questions about how you feel about this type of contraception
- Schedule your next visit

Optional Specimen Collection

As an optional part of this study, at the Enrolment visit, we would like to collect about 1 teaspoon of blood and store it to test after this study is over. If you agree to provide this additional sample, it will be stored for future testing to see how your body responds to 6-month DMPA SC (this type of testing is also known as pharmacogenomics). The sample will be stored at the Chalmers Centre and later will be shipped to a lab outside your country (most likely in the US) for additional storage and testing like some of your other study samples. Your sample may be stored for up to 10 years after the end of the study. It will be identified by a code number only, never by your name. We will not share these results with you or request additional consent from you before the future testing. Since this is optional, you do not have to agree to provide this additional sample to be in this study.

Follow-up Visits

You will have 4 scheduled clinic follow-up visits at Months 3, 6, 9 and 12. The first 3 clinic follow-up visits will last about 30 minutes. At each of the follow-up visits we will:

- Check your vital signs and weight
- Check each place on your skin where you received a DMPA SC injection at a previous visit. We may take a photograph of a reaction to the DMPA SC injection
- Ask you about any new or worsened medical problems and if you took new drugs since your last visit
- Collect a urine sample for a pregnancy test
- Check your diary and ask you questions about how you feel about your bleeding so far
- Provide several pregnancy tests with instructions when and how to use at home
- Collect or verify your contact information
- Schedule your next visit

At Month 6, we will also:

- Ask you questions about how you like the contraceptive method so far
- Take a blood sample from your arm (about 1 teaspoon) to measure the level of MPA in your blood. We will run this test only if indicated.
- Draw blood from your arm (about 1 teaspoon) to measure the level of estradiol in your blood
- Give you your 2nd injection of DMPA SC in either your abdomen or thigh, the same location where you had your first injection, but on the opposite side of your body (for example, if your first injection was on your right side, the second injection will be on your left side).
- Mark and take a photo of the injection location

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Month 12

Month 12 may be your final visit if you do not qualify for or do not choose to participate in the Extended Follow-up Sub-study described below. At this visit, which will last about 1 hour, we will:

- Check your vital signs and weight
- Ask you about new or worsened medical problems and new drugs you are taking since your last visit
- Collect a urine sample for a pregnancy test
- Give you a physical examination
- Check both places on your skin where you received a DMPA-SC injection. We may take a photograph of a reaction to the injection
- Check your diary and ask you questions about how you feel about your bleeding
- Take a blood sample from your arm (1 teaspoon) to measure your levels of haemoglobin and haematocrit
- Draw blood from your arm (about 1 teaspoon) to measure your levels of MPA. We will run this test only if indicated.
- Draw blood from your arm (about 1 teaspoon) to measure levels of estradiol
- Ask you questions about how you like the contraceptive method
- Ask you about future pregnancy and contraception plans and provide your desired contraception method during your visit or at a rapid access appointment

Pregnancy Procedures

During the study:

There is a risk that you may become pregnant during the course of the study. You will be tested for pregnancy each month you are in the study. We will provide you with pregnancy test kits and explain how to use them at home to test for pregnancy during the months you are not scheduled for a clinic visit (months 1, 2, 4, 5, 7, 8, 10, 11). If you do the test at home, we will contact you to remind you to take the pregnancy test and we will contact you again to ask for the result. We may ask you to take a photo of the result and send it to us. We will also test you for pregnancy using a urine pregnancy test in the clinic during follow-up visits at Months 3, 6, 9 and 12 to make sure you are not pregnant.

If your pregnancy test is positive (done in the study clinic or elsewhere) any time during the study, we will confirm it by a blood test and/or ultrasound in the clinic. We will also take a blood sample for MPA testing if you are confirmed to be pregnant during the study. If you become pregnant during the study, your study participation will end, and you will have your final study visit. However, we will contact you about the status and outcome of your pregnancy.

If you become pregnant, all options are available to you as if you were not in the study. If you wish to end the pregnancy we will link you to the local abortion service.

If you decide to continue your pregnancy, we will link you to your community midwifery team. Be aware that roughly 1 in 4 pregnancies end in miscarriage naturally, we do not suspect that a pregnancy conceived during the study would be more or less likely to miscarry.

We will ask you about the final outcome of the pregnancy and if you have a baby, we will remotely check the baby's medical record to check it is healthy up to 1 year after birth.

If you leave the study early

If you become pregnant in the first 40 weeks (approximately 9 months) after receiving the first injection and never received the second injection, we want you to let us know. If you become

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pregnant within 27 weeks (approximately 6 months) after receiving your second injection and you left the study early, we want you to let us know. We may collect information about any potential pregnancies from central NHS records, your hospital, and/or your GP. If you do not want this to happen, tell us and we will stop. For both scenarios, we will ask you to return to the clinic for confirmation by blood test and/or ultrasound (if possible). We will contact you about the status and outcome of your pregnancy.

If you plan to become pregnant after the study

One of the potential side effects of DMPA is delay in ability to become pregnant. It may take at least 1 year after your last injection of 6-month DMPA SC for you to become pregnant. If you want to become pregnant after you finish the study, we will ask you to let us know if and when you become pregnant. If we don't hear from you, we may call you to find out if you became pregnant before the study ends.

Extended Follow-Up Subset

At your month 12 visit, if you choose to use a non-hormonal contraceptive or no contraception after study completion, we will ask you if you want to participate in an optional extended follow-up phase. If you are interested in participating, more information will be provided at your month 12 visit.

What are my responsibilities as part of this study?

- Come to all your scheduled study visits or tell the study staff that you need to reschedule
- Complete your diary on a daily basis to record your vaginal bleeding, menstrual pain, sexual activity and condom use
- Complete your pregnancy tests monthly
- Use DMPA SC as your only method of contraception during the study
- Return to the clinic and/or contact the study staff as soon as possible if you think you may be pregnant anytime during the study and in special situations as described above
- Not to disturb the area (on your thigh or abdomen) where you got your injection by massaging it or using a plaster
- Return to the clinic to repeat lab testing if we need to confirm your lab result
- Tell the study staff about any health issues you have or changes in health, even if you think they are unrelated to the study. If you seek care outside of the study we may request those records for the purpose of the study. This includes, but is not limited to:
  - A reaction where you had your injection
  - STI testing
  - Pregnancy testing

What are the possible risks to me?

Pregnancy

We estimate the risk of unintended pregnancy in this study to be low but it is unknown so there is a chance you may become pregnant during the study. We will test you for pregnancy before you enrol and each month during the study, at study visits, and at any time you have signs of pregnancy or think you might be pregnant to make sure you are not pregnant. We will also give you urine pregnant tests so you can use them at home if you cannot return to the clinic in time. We will refer you for medical care at NHS in the unlikely scenario that you become pregnant. However, many

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studies have found that babies who are exposed to DMPA while in the womb do not have a higher risk of birth defects or health problems.

Return to Fertility

Your usual level of fertility will return when the last injection has worn off. This time varies in different people. Although you may be able to get pregnant quickly, it is more likely to take a year or longer after your last injection before you get pregnant. However, if you are concerned about not getting pregnant at any time after you leave the study, you may contact this clinic for a consultation.

Menstrual Changes

While using DMPA, most people have irregular bleeding, spotting or no bleeding at all. Changes to your vaginal bleeding are not dangerous for your health. Regular bleeding is expected to return when most of MPA is cleared from your body.

Injection Site Reactions

There is a chance that you will have skin reactions where you receive the injections. In several previous studies of subcutaneous DMPA, 5% (5 in 100) of users reported injection site reactions, and 1% (1 in 100) had persistent skin changes, described as small areas of induration or atrophy. In one study of subcutaneous DMPA, 6% (6 in 100) of users reported hypopigmentation (patch of your skin are lighter in colour than your surrounding skin) and 4% (4 in 100) reported atrophy (or dimple) at the injection site. No injection site reactions were found to be serious or severe. During this study we may photograph injection site reactions at any time.

Weight Gain

Some people gain weight while using DMPA (about 3-5 pounds in a year). It is not clear whether this weight gain is natural or due to the drug. It is possible that you will gain a small amount of weight during this study.

Sexually transmitted infections (STIs) and/or human immunodeficiency virus (HIV)

According to World Health Organization (WHO), it is safe for people who can become pregnant who are at high risk of STIs including HIV, to use DMPA.

DMPA cannot protect you against STIs, including HIV. The main ways that a person can reduce the risk of HIV infection and other STIs are to: abstain from sexual intercourse; use condoms during intercourse; not share IV drug needles; and have no more than one sexual partner who is HIV-negative. If anytime during the study you have sex that you think may put you at risk of STIs and/or HIV, you should use condoms. Condoms and education about their use, or other ways you can prevent getting an STI or HIV, can be provided by study staff. If you have been exposed to or have an STI or HIV while participating in this study, we will refer you for care outside of the study.

Bone Mineral Density

Use of DMPA for more than 2 years may weaken your bones (the condition known as osteopenia and osteoporosis which may increase the risk of broken bones). It is not expected that getting two injections of subcutaneous 6-month DMPA in this study will have a substantial effect on your bones due to the short duration of the study (12 months).

Cancer

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Some studies found a slightly increased risk of breast cancer among women using DMPA for 12 months or longer. It is unlikely that getting two injections of subcutaneous 6-month DMPA in this study will lead to breast cancer. To make this risk even lower, we will ask if you have current or history of breast cancer and do a breast examination before you join the study to make sure you do not have any lumps in your breast that may indicate breast cancer. We also enrol only people 35 years of age or younger in this study. Risk of breast cancer in this age group is low. We will not enrol you in this study if you have a history of breast cancer.

Severe Allergic Reaction

Severe allergic reaction to DMPA, also known as anaphylactic reaction, is rare. Such reactions usually happen right after the injection. We will ask you to remain in the clinic for observation for at least 15 minutes after each injection where we have special drugs to treat severe allergic reaction and easy access to emergency care in the unlikely event of you having such reaction. We will also tell you about possible signs of anaphylactic reaction prior to leaving the clinic. You should seek emergency care immediately if you have signs of anaphylactic reaction after you leave the clinic.

Side Effects

In addition, you may experience the following side effects:

- acne
- headache
- tiredness
- decreased sexual desire
- breast pain
- depression

If you have a side effect after an injection, the drug cannot be removed immediately so the reaction may continue for some time. Most of the side effects do not pose serious risk to your health and go away with time without clinical care. However, some side effects may persist until most of the MPA is cleared from your body. This time varies by person but could take 9 or more months from the last injection. Please let us know if you experience a side effect, and we will let you know if any special care is needed. If you have a health problem during the study and seek care at another clinic, you should tell the physician that you are in this research study. Although we have a lot of safety information for DMPA, there could still be risks from this product that are not foreseen or known.

Blood Draw

This study includes frequent blood draws of small amounts of blood, about 1-3 teaspoons. It is possible that you may feel some pressure or discomfort while your blood is being drawn and you may have a small bruise where the blood was drawn. There is also a small risk of infection with a blood draw.

Ultrasound

If you have a positive pregnancy test result during the study, the pregnancy may be confirmed by an ultrasound. This ultrasound may be transabdominal or transvaginal. During the transvaginal ultrasound, you will be asked to undress from the waist down and lie on an examination table. A special instrument, of the width of two fingers, will be inserted into your vagina. The special instrument will be covered with a new condom and lubricating gel will be applied to it for ease of insertion. This procedure is usually not painful but may cause discomfort when the instrument is

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inserted and/or moved in your vagina. It may also cause anxiety or embarrassment. During the transabdominal ultrasound, lubricating jelly is applied directly to your abdomen and a wider, flat instrument is used on your skin to conduct the ultrasound.

Gynaecological examination

We will perform a gynaecological examination to make sure you do not have medical contraindications to be in the study. Also, if you have any gynaecological issues during the study we will know if it is a new condition or same condition that you had before the study. During the gynaecological examination, you will be asked to undress from the waist down and lie on an examination table. This examination is similar to the examination that you undergo for a Cervical smear. It usually does not hurt but may cause slight discomfort, anxiety, or embarrassment.

Non-Medical Risks

Non-medical risks may include a breach of confidentiality (someone finding out that you are in this study that is not authorized to know this information), potentially missing work to come to study visits, and answering questions about potentially sensitive subjects like sexual history and keeping a diary about your bleeding, sexual activity, and condom use. Again, we will do our best to prevent anyone outside the study from knowing about you and your participation in this study. We will also do our best to accommodate your availability when scheduling clinic visits. If you experience any of the issues described above, please let the study staff know.

If you think that having a copy of this ICF could contribute to others knowing that you are taking part in the study, you are not obligated to take it.

Breach of Confidentiality

While we will make every effort to keep your information private during and after your study participation, it is possible that there could be a loss of confidentiality at some point during or after the study. We will tell you if we know that this had happened.

Are there any possible benefits to me?

There is no direct benefit to you for being part of this study. We hope that the findings from this study may help us develop a new longer-acting contraceptive injection and help others who want effective and long-acting protection against pregnancy in the future.

Confidentiality

We will do our best to prevent anyone outside the study from knowing about you and your participation in this study. All study files that list your name will be kept in a locked file and may be uploaded to a secured website for remote monitoring of the study by FHI 360 staff or contractors. FHI 360 staff and contractors working on the study may look at your study and clinic records for information related to the study. FHI 360, the study funder (USAID), ethics review committees and/or the regulatory agencies may also review your records. We may also need to review your medical records relating to any care you received during or prior to the study, even if you receive this care elsewhere. We will make every effort to protect all the information you give us secure at Chalmers Centre and FHI 360.

Study data collected from you and other participants will be shared with FHI 360 and the regulatory agencies overseeing this study. When the data are shared, only a number will identify you, not your name. Your study data will also be shared with USAID and in a public database, but will not contain your name, identity or contact information.

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If you miss a scheduled visit, we may contact you at home by phone to schedule another visit. When this contact is made you will not be identified as being in this research.

If you agree to take part in this study, you will also have the option to allow the research team (within the sponsoring organisation) to securely store your contact details and agree to be contacted about other ethically approved research studies. You will only be contacted by a member of this research team to determine if you are interested in taking part in another research study. Your verbal consent may then be sought to pass your contact details to another research team within the University of Edinburgh and/or NHS Lothian. Agreeing to be contacted does not oblige you to participate in further studies.

Are there any costs to me if I join the study?

There will be no anticipated costs for you to participate in this study. If you have a lab result or finding on your physical or gynaecological examination that requires medical follow-up and/or care, or become pregnant while participating in the study, you will be referred to NHS.

Will I receive compensation during the study?

Below is a table providing information on the compensation you will receive per visit you complete for your time and transportation. If you leave the research study early, we will compensate you only for the visits you attend. Participation in the study will not affect fees, payment, billing, or reimbursement for any other services at the clinic.

Visit Type	**Amount**
Screening Visit	£100
Enrolment Visit	£100
Reinjection Visit (Month 6)	£100
Follow Up Clinic Visits (Month 3, 9)	£50 each
Pregnancy Testing Only (Months 1, 2, 4, 5, 7, 8, 10, and 11)	£6 each
Final Visit (Month 12)	£100
Total Compensation	£548

Voluntary participation

Participation in this study is voluntary. You can decide if you want to be in this study or not. If you choose to join the study, you can change your mind at any time and leave the study. You do not have to answer any questions you do not want to answer. Your choices will not affect any benefits or medical care to which you are entitled. If you decide to withdraw before this study is completed, we will keep any data and/or samples that you have provided during the study unless you ask us not to keep this information.
Also, you may be asked to stop your participation in the research if:

- the research doctor/clinic staff feels it is best for you, or
- you are not able to follow the research procedures, or
- the research is stopped.

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Alternatives to participation

Being in this study is voluntary, so you should decide if you want to join this study. Other contraceptive methods are available outside of the study. You may discuss seeking different contraception with other providers at the clinic.

New information about the study

We will communicate to you any new information found during the study that may affect whether you want to continue to be in the study.

What if I have a problem or have questions?

If you have any questions about this study, you can contact:

Anne Johnstone
Email: Anne.Johnstone@ed.ac.uk
Research Mobile: 0797360871

What if I get sick or have a health problem?

If you experience a non-emergency health problem, you should inform the study clinic staff right away at any time during the research by calling:

Anne Johnstone
Email: Anne.Johnstone@ed.ac.uk
Research Mobile: 07973 760 871

Karen McCabe
Email: kmccabe@exseed.ed.ac.uk
Research Mobile: 07973 760 871

What if I experience a medical emergency?

- Seek emergency care immediately or call 999 for assistance
- Ask your emergency provider to contact:

  Professor Sharon Cameron
  Email: Sharon.cameron@ed.ac.uk
  Phone: 0131 536 2091

If you are sick or have a health problem because of being in this research study, medical care as determined by the doctors in this study will be available to you. This additional medical attention that is required because of a health problem caused by your participation in the study will be covered without cost to you and will be NHS care.

What are my rights as a participant?

This research was reviewed and approved by the South Central - Oxford B Research Ethics Committee and FHI 360's Ethics Committee (Protection of Human Subjects Committee). These committees review research studies to help protect participants. If you have any questions about

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how you are being treated by the research staff, or your rights as a research participant, you may contact the chair/director of the local IRB:

If you wish to make a complaint about the study, please contact:

Patient Experience Team
2 – 4 Waterloo Place, Edinburgh, EH1 3EG
Email: feedback@nhslothian.scot.nhs.uk
Phone: 0131 536 3370

FHI 360, the sponsor of this trial, cares about your safety. Staff working on this project should never threaten, harass, or harm you; ask you for money, favours, or sex in exchange for goods, employment, or services; or ask you for sex acts in exchange for money. If any of this happens or is suspected, you can report the incident confidentially through one of the methods below. Reporting is always free.

Email: compliance@fhi360.org
Tel: 0808 189 1053
www.fhi360.org/anonreportregisry (anonymous reporting)

Privacy Notice

This privacy notice applies to all personal information that the trial sponsor, FHI 360 (known as the data controller) and the researchers identified in the informed consent, collect or process about you in connection with your participation in this clinical trial. Personal information is information about you through which you can be identified (including where you can be identified by combining the information with other information). Some of this personal information may include information which is classified as "sensitive" under local privacy laws (for example, information about your physical and mental health).

As part of this clinical trial, the following types of personal information related to your participation may be collected from you:

- Contact information;
- Health information;
- Racial or ethnic origins;
- Religious or philosophical beliefs;
- Sexual orientation;
- Genetic data;
- Information about your responses to the research procedures or interview questions.

The legal basis for collecting and processing your personal information is one or more of the following:

- We have a legitimate interest in collecting the data as part of your participation in the clinical trial; and/or
- As necessary by law.

Chalmers Sexual Health Centre
2A Chalmers Street
Edinburgh EH3 9ES

Telephone : 0131 536 1070
Fax : 0131 536 1609
www.lothiansexualhealth.scot.nhs.uk

Your data will be used and/or stored as long as needed for the research study and consistent with applicable laws and regulations.

Your Rights

- You have the right to see the information being collected about you in the study. To ensure integrity of the study, you will not be able to review some of the data until after the study has been completed.
- You have the right to request corrections to your personal information if it is inaccurate.
- You have the right to limit the collection and use of your personal information under certain circumstances (for example, if you think that the information is inaccurate).
- You have the right to request the deletion of your personal information if you are no longer participating in the study. However, there are limits on your ability to request deletion of your personal information such as if deletion would seriously impair the integrity or the efficacy of the study or if your personal information is needed to comply with legal requirements.
- You have the right to file a complaint with your local data protection authority.

Withdrawal from the Study

If you withdraw from the study, you will no longer be able to participate in the study. No new samples will be collected from you by the study team. Your withdrawal has no effect on the lawfulness of the data processing that occurred prior to your withdrawal.

After your withdrawal, your data and personal information may still be maintained to maintain the integrity of the study, to satisfy any legal or regulatory requirements including reporting and retention requirements, and/or for any other purposes permitted under applicable data protection and privacy laws. Your personal information also may be anonymized so that the information does not identify you personally, and such anonymized information may be used for further research.

Security

We implement technical and organizational measures to ensure a level of security appropriate to the risk to the personal information we process. These measures are aimed at ensuring the ongoing integrity and confidentiality of personal information. We evaluate these measures on a regular basis to ensure the security of the processing. For more information on the appropriate safeguards in place, please contact us at the email address below.

International Data Transfer

Your data will be used and shared with the researchers and sponsors on this research study as well as government regulators and as fully described in the Informed Consent Form. Your personal information may be shared with individuals outside your country, including the United States, and will be treated in compliance with applicable data protection laws. Data privacy and protection in those countries may not offer the same level of protection as those in your own country.

Contact Information

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If you have questions or concerns regarding the way in which your personal information has been used, please contact your study doctor or the Data Protection Officer at: privacy@fhi360.org.

Edinburgh Community Healthcare Partnership

Chalmers Sexual Health Centre
2A Chalmers Street
Edinburgh EH3 9ES

Telephone : 0131 536 1070
Fax : 0131 536 1609
www.lothiansexualhealth.scot.nhs.uk

NHS Lothian

Informed Consent Form

A Phase 3, Open-Label, Multicentre Study to Evaluate Contraceptive Efficacy and Safety of Depot Medroxyprogesterone Acetate (150 mg/mL) Injected Subcutaneously Every Six Months

FHI 360 Study Number: 1706176

Version 5.0

Study Sponsor: FHI 360

Study Investigator: Professor Sharon Cameron

Site No. 005

Site Name and Address: Chalmers Centre

2a Chalmers Street, Edinburgh EH3 9ES
01315361070 or 0131 536 1010

Participant Study Number: ___ ___ ___ ___

Participant Name: _____

This form was explained to me in my native language. I have been told what will happen if I take part in the study titled, "**A Phase 3, Open-Label, Multicentre Study to Evaluate Contraceptive Efficacy and Safety of Depot Medroxyprogesterone Acetate (150 mg/mL) Injected Subcutaneously Every Six Months**", including the risks and benefits.

Please initial each row below to indicate you agree to the statements. Initials

I have read and understand the participant information sheet Version 5.0 dated, 12 October 2023, for the above study and have had time to consider the information.	
The study has been explained to me. I have had the chance to ask questions and have had all these questions answered to my satisfaction. I had enough time to decide whether or not to participate.	
I understand that participation is voluntary. I know that I may decide at any time not to participate after all or to stop participating in the study without my medical care or legal rights being affected. I do not need to give a reason for this.	
I give consent to collect and use my personal data and bodily material for answering the research question in this study and for registration of the study drug. I agree to the transfer of my coded personal data outside the UK.	
I understand that the information collected about me may be used to support other research in the future.	
I understand that coded blood samples and personal data collected for MPA testing will be sent to a lab outside the UK for analysis.	
I know that for study monitoring purposes some individuals could have access to all my data. These people are listed in this information sheet. I consent to that access by these people.	

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I agree that my General Practitioner is informed about my participation in this study and can provide the study doctor with information from my medical records. The study doctor can also provide my General Practitioner with medical information about me.	
The benefits, risks, and procedures for the collection of an additional sample have been read and explained to me. I have had my questions about the research answered to my satisfaction.	
I have freely signed this Participant Informed Consent Form prior to any study-related procedures being performed.	

The following are OPTIONAL only (i.e. you can still take part in the study if you mark "No"):	
I agree to provide an additional sample.	Y N
I give the researchers permission to keep my contact information and to contact me for future research projects.	Y N

Study staff will offer me a copy of this consent form. By signing below, I voluntarily agree to be in this research study.

_____
Printed name of participant

_____ _____
Signature of participant Date

I have carefully explained to the study participant the nature and purpose of this study. The study participant has been given enough time to decide whether to participate in this study or not. The study participant has had a chance to ask questions and receive answers about this study prior to signing this informed consent.

_____
Printed name of person who obtained consent

_____ _____
Signature of person who obtained consent Date