Premature Ovarian Insufficiency Study of Effectiveness of hormonal therapy (the POISE study)

Participant Information Sheet

Final Version 4.0, 07 Nov 2025

IRAS Project ID: 279224 / Sponsor reference number 121197

1. You are invited to take part in our research trial

The POISE trial is looking at exploring which hormone treatment works best for women with premature ovarian insufficiency (POI). Oestrogen treatment is recommended, but it's not clear which is the best type. This study aims to find out.

The study is supported by patient groups including the Daisy Network and Turner Syndrome Support Society. It is funded by the National Institute for Health and Care Research, and it is being conducted at more than 20 NHS centres across the UK.

This information sheet is to help you understand why the research is being carried out and what it will involve for you if you decide to take part.

Please take time to read this information and ask us if there is anything that is not clear to you or you would like more information.

It is entirely your decision whether to take part in this trial. If you agree to take part, you are free to withdraw at any time without giving a reason. If you choose not to take part, your care will continue in the normal way.

2. A summary of the trial

The study will involve almost 300 women with POI living throughout the UK. They will be divided into 2 groups allocated randomly by a computer. Depending on the group participants are assigned to, they will take either combined oral contraceptive (COC) or Hormone Replacement Therapy (HRT).

We do randomised trials when we don't know which way of treating patients is best. To find out which treatment is best for relief of symptoms and reducing long-term health risks of POI, we need to compare different treatments. Women in the HRT group are also offered a further comparison, either taking HRT by mouth (tablets) or through the skin (patches/gel).

Everyone taking part in the study is asked to fill in questionnaires to assess POI symptoms and the effect on women's lives, the acceptability of treatment and any side-effects. They also attend some appointments to monitor changes in bone and heart health over at least 2 years on treatment.

All the information from the study will be kept safe and confidential. At the end of the study, the information that has been collected will be analysed. The results will be published, and the answers will be shared with women taking part (if they wish) as well as health professionals. The results are expected to improve medical care for women with POI in the future.

3. What is the purpose of the trial?

POI occurs when the ovaries lose their normal function before the age of 40. POI causes symptoms like missed periods, hot flushes, low libido, mood changes, and tiredness as well as long-term health risks of bone thinning, heart disease, and memory issues. The symptoms of POI can be distressing and have an impact on quality of life.

POI is usually treated with a combined oral contraceptive pill (COC) or hormone replacement therapy (HRT). Both these treatments replace missing hormones, improve symptoms, and reduce long-term health risks. There are benefits and risks of each treatment.

The POISE study aims to find out what is the best treatment for women with POI in both the short and long term.

4. Why have you been invited to take part?

You have been invited to take part in this trial as you have been diagnosed with POI and are aged between 18 and 39. We will check that the study treatments are suitable for you before you start. If you are planning to become pregnant within the next 12 months, you will not be able to take part.

5. Do you have to take part?

It is up to you whether or not you take part in the trial. Even if you agree now, you are free to withdraw at a later date if you wish. We will talk to you about the trial and answer any questions you may have. If you agree to take part, we will ask you to sign a consent form (this may be provided online or by email).

6. What would taking part involve?

Starting the study

If you are already taking hormones to treat POI, you will need to stop treatment for 4 weeks so we can assess your health without it.

Before starting study treatment, you'll have clinic tests (blood pressure, height, weight, bone density scan) and fill in questionnaires about your symptoms, lifestyle, and health.

The bone density measurement may be at a different time and/or location to the other tests. These initial tests will need to be completed at your treating clinic. During the bone density scan, you will need to lie still on your back on a flat, open x-ray table. This usually takes 10-20 minutes. The results will be discussed with you at your next clinic appointment.

Some clinics may offer optional blood, urine, or chromosome (genetic) tests to look at bone health and cardiovascular health in more detail. Results are shared at your next visit. You can still join the study without giving these samples should you prefer not to.

If you do choose to provide blood samples, you will have a morning appointment and will be asked to fast before the blood test is done. This means that you should have nothing to eat or drink except plain water for 12 hours before the blood test. However, you can continue to take any prescribed medications with water only. About 30ml (6 teaspoons) of blood will be taken for the tests.

Oestrogen treatment

After initial tests, you'll be randomly assigned to take either COC or HRT. This means that you cannot choose which treatment you take. Your study doctor will give you a prescription and you can start the treatment straight away.

If you are in the COC group, we recommend running 3 packs together, this will involve taking a daily tablet for 9 weeks, then a short break (4-7 days). Your study doctor can explain this and alternative ways to take it.

If you are in the HRT group, you will be asked whether you have a preference to take it as a tablet, patch or gel. If you have no preference, it will be randomly chosen for you. HRT usually includes oestrogen and progesterone, but if you've had a hysterectomy, you may only need oestrogen. HRT isn't reliable contraception, non-hormonal methods are advised if relevant to you. Your study doctor will discuss the best option with you.

We know that some women will need to change their treatment during the study. It is possible to try different brands of COC or different types of HRT (e.g. tablet or patch) if you feel what you were first prescribed is not working for you. If this is the case please speak to your study doctor, who will discuss your options with you.

You'll be asked to stay on your study treatment for at least 2 years and, if possible, we will keep in contact for up to 5 years. However, we know that some women may want to change or stop the allocated study treatment. We ask that you speak to your study doctor first before making changes. They can discuss it with you and inform your GP what to prescribe for you. If planning pregnancy, let them know so that they can support you.

Your study doctor will prescribe your treatment initially, and we will notify your GP so they can provide repeat prescriptions. HRT may incur prescription charges in England, but you can apply for an HRT pre-payment certificate (**https://www.gov.uk/get-a-ppc/hrt-ppc**). COC is free of charge.

Follow-up

Measuring your blood pressure and weight will be repeated at 3 months, 6 months, and 12 months, then yearly.

These check-ups are usually done by your study team at the clinic, but your GP or pharmacy may help if needed.

You'll also complete questionnaires about your symptoms, lifestyle, sexual activity, and work life. These are sent by email, or by post if you prefer. All your information will be kept safe and confidential.

Bone density scans will be repeated at 1 year, 2 years, and at 5 years if you are continuing in the study. These may require extra visits, and may be at a different place from your clinic, as they're not always part of routine care.

If you've agreed to give blood and/or urine samples, these will be taken again at 3 months, 1 year, and at 2 years (blood only).

If you become pregnant or are planning pregnancy, please contact your study doctor.

With your permission, we will inform your General Practitioner (GP) about your participation in this trial.

Your name and telephone number will be shared with Esendex, our text messaging provider and their subprocessors, and will be used to send you text message reminders about the trial and trial questionnaires whilst you are participating in the trial.

7. What are the possible benefits of taking part?

You'll be offered POI treatment whether or not you join the study. If you do take part, your health will be monitored more closely, and you'll have access to a study doctor in between routine clinic visits. Taking part in the trial may not directly benefit you, but the information we collect from this trial may help us to treat people with POI in the future.

There's no payment for joining the study. However, you'll receive up to £110 in vouchers (£20 at 3- and 6-months clinic visits, and £35 at 1- and 2-years clinic visits) This is a recompense towards the additional costs associated with missing work etc to attend trial-related appointments.

8. What are the possible disadvantages and risks of taking part?

Study treatment:
COC and HRT are standard POI treatments, with possible side-effects such as headaches or irregular bleeding. Serious side-effects are rare. Your doctor will discuss options and check for any medication interactions.

Bone density measurements:
Bone density is measured using low-dose radiation, each scan is less than 2 days of natural background radiation and much less than a standard X-ray. You must not have this scan if you are or might be pregnant.

Blood samples:
Blood samples are routine though they may cause brief discomfort, bruising, or swelling, which usually clears up quickly.

9. What if there is a problem?

If you have concerns or questions about any aspect of this trial, you should ask to speak to the local researchers. Their contact details are at the end of this information sheet.
If any questions remain you can contact the trial coordinating centre:

Email: poise@nottingham.ac.uk. If you remain unhappy and wish to complain formally, you can do this through the National Health Service (NHS) Complaints Procedure via your local Patient Advisory and Liaison Service (PALS) <insert Local PALS details>.

In the event that something does go wrong and you are harmed during the research then you may have grounds for a legal action for compensation, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

10. What will happen if I don't want to carry on with the trial?

You are free to withdraw at any time, without giving any reason, and without your legal rights being affected. If you would like to withdraw, contact your local researchers / NCTU Trial team and they can organise this for you. Their contact details are at the end of this information sheet. If you withdraw the information collected will not be erased and this information may still be used in the project analysis.

11. How will information about me be used?

We will need to use information from you and from your medical records for this research project.

This information will include your (initials, NHS/CHI number, name, contact details). People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

University College London (UCL) is the sponsor of this research.

UCL is responsible for looking after your information. We will not share your information related to this research project with any other organisations.

We will keep all information about you safe and secure by:

- Following and adhering to the laws relating to General Data Protection Regulation (GDPR)
- Having strict access controls on our electronic systems
- Deleting your personal data (as outlined in this information sheet) when it is no longer required
- Keeping the details we have to contact you separate from the trial data.

12. What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study. Your details will be deleted after the study. All data will be securely destroyed after 25 years.

13. Where can you find about more about how your information is used?

You can find out more about how we use your information:

- Our leaflet at **www.hra.nhs.uk/patientdataandresearch**
- by sending an email to our Data protection officer at data-protection@ucl.ac.uk
- by reading our privacy statement **https://www.ucl.ac.uk/legal-services/privacy/participants-health-and-care-research-privacy-notice**
- by asking one of the research team
- by sending an email to poise@nottingham.ac.uk
- by ringing us on <insert trial phone number>

14. Who is organising and funding this study? How has it been approved?

The trial is being organised by the University College London (the Sponsor) and coordinated by the Nottingham Clinical Trials Unit (NCTU). The funding for the trial is provided by the NHS's research arm, the NIHR Health Technology Assessment Programme. All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This trial has been reviewed and given favourable opinion

by a Research Ethics Committee.

The Daisy Network and Turner Syndrome Support Society (UK) are supporting the study. Women with POI have helped design the study and are involved in overseeing how it runs.

15. What if relevant new information becomes available?

Sometimes we get new information about your treatment during the trial. If this happens your research doctor will tell you about this new information and discuss whether you should continue in the trial. If you decide not to carry on, your research doctor will make arrangements for your care to continue as normal. If you decide to continue in the trial he/she may ask you to sign a new Informed Consent Form.

16. What will happen to any samples I give?

If you choose to give blood or urine samples (optional), they'll help us study your bone and heart health. Heart-related blood tests will be analysed by the hospital lab, and your doctor will discuss any abnormal results. Bone-related samples will be stored securely and analysed at the end of the study. Stored samples will be labelled with your study number, initials, and date of birth.

If you agree, leftover blood may be stored for up to 5 years for future, ethically approved, research on POI, including genetic studies. You won't be identified or receive individual results.

You can still provide blood samples for testing within this study, even if you don't want your blood stored afterwards; just indicate this on the consent form. If you don't want your samples stored, they'll be safely disposed of.

17. What happens at the end of the study?

This is a very long study. We will look at the results 2 years after the last participant has agreed to take part.

When the trial ends, your healthcare/treatment will continue as normal. You may want to continue the same treatment or may change it, particularly as you get older, with guidance from your usual doctor. It is recommended that women with POI should take hormonal treatment until the typical age of menopause. If you withdraw from the trial, we will need to keep and use the data collected up to your withdrawal. At the end of the trial the results will be published in scientific medical journals and presented at conferences. You will not be identified in any publication. We will send you a newsletter with a summary of the trial findings, unless you ask us not to.

18. How to contact us

Contact details of your local care team who will be your main point of contact for the duration of the trial;

- <insert contact details here>

This project is funded by the National Institute for Health and Care Research (NIHR) HTA Programme (project reference NIHR128757). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

FUNDED BY NIHR | National Institute for Health and Care Research