Imperial College
London

Institute of Reproductive and Developmental Biology
Hammersmith Hospital
Du Cane Road
London
W12 0NN
Tel: +44 (0) 207 594 2109

s.franks@imperial.ac.uk
www.imperial.ac.uk
www.med.ic.ac.uk/divisions/58/irdb.asp

Stephen Franks MD FRCP FMedSci
Professor of Reproductive Endocrinology

Patient Information Sheet

REC reference number: 08/H0707/152
Full title of study: Understanding disorders of ovulation in women with polycystic ovary syndrome (PCOS): investigating the action of insulin on granulosa cells

We would like to invite you to take part in a research study. Before you decide, you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Talk to others about the study if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

Polycystic ovary syndrome (PCOS) is the commonest hormone disorder in women, affecting between 5-10% of women of reproductive age. It is a major cause of infertility but it is also associated with metabolic disorders including type 2 diabetes. Abnormal production and/or action of pituitary gland hormones called gonadotropins are implicated in the cause of PCOS but, to date, we have only limited knowledge about the precise mechanisms that are involved. Importantly, many women with PCOS have insulin resistance, a condition in which higher than normal levels of insulin are needed to keep blood sugar levels normal. We have shown that high insulin levels have an adverse impact on the ovary, interacting with gonadotropins to futher disturb the normal function of ovarian target cells.

The purpose of this project is to see how gonadotropins act on granulosa-lutein cells (GLCs) in the ovary. These are the cells that line the inside of follicles (egg sacs) from which the egg is collected at the time of in vitro fertilization (IVF). Once the egg has been retrieved, these cells are usually thrown away but they are vey useful for our research because they contain receptors (target sites) for the gonadotropins and for insulin. Using these “spare’ cells we hope to better understand why they behave abnormally in PCOS. This information will provide insight into the cause of abnormal function of these cells and indicate targets for medical intervention. The longer term aim is to develop new, better-targeted and more effective drugs to treat PCOS.

Granulosa-lutein cells will be obtained at the time of egg collection for IVF from 2 groups of women: those with normal ovaries and those with PCOS. These “spare” cells will be collected from the fluid and used in research. We will examine the effects of gonadotropins and insulin on (a) production of hormonal steroids and (b) glucose metabolism, comparing the results in normal and polycystic ovaries.

Why have I been chosen?

You have been invited to take part in this study because we are hoping to include women who are you undergoing IVF and who either (1) are known to have polycystic ovaries or (2) have normal ovaries and a history of regular ovulation. We

will then be able to compare results of our studies in ovarian cells from women with PCO with those from women who have normal ovaries.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive. although non-identfiable data may be kept

What are the possible benefits of taking part?

There are no direct advantages or benefits to you from your participation in this study but we hope to learn more about how insulin and gonadotropins affect the ovarian cells in normal and polycystic ovaries with the aim of improving treatment of polycystic ovary syndrome in the future.

What will happen to me if I take part?

As described above, granulosa-lutein cells are found in the fluid collected from the eggs but are usually discarded. We are asking for your permission to collect these “spare” cells to use in research at time of egg collection for IVF. All the required information and material will be available at the time of your planned IVF cycle and no futher visits or tests will be necessary for this research project. No personal identifiable data will be linked to the cells after they have been collected. At the end of the study, any remaining cells will no longer be stored and will be destroyed.

If we unexpectedly find anything abnormal that might affect your health, we will discuss this with you and the next step would be to inform your GP for further investigation

There are no extra risks or side effects to you other than those that are associated with IVF or ICSI. Your participation will be confidential.

What do I have to do?

You need do nothing other than donating the spare ovarian cells that would otherwise have been thrown away after the eggs have been collected for IVF. There will no additional restrictions to your lifestyle over and above those that you may have been advised about before undergoing IVF.

What are the possible disadvantages and risks of taking part?

There are no additional risks to those that you will have been informed about in undergoing an IVF cycle.

What are the possible benefits of taking part?
We cannot promise that the study will help you directly but the information that we might help improve the treatment of women with PCOS

What if something goes wrong?

Imperial College London holds insurance policies, which apply to this study. If you experience harm or injury as a result of taking part in this study, you may be eligible to claim

compensation without having to prove that Imperial College is at fault. This does not affect your legal rights to seek compensation.

If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform Professor Stephen Franks (Tel: 020 7594 2109; email: s.franks@imperial.ac.uk)

Getting a second opinion

If you are unsure about any of the points above you can discuss them with the consultant looking after you, or any of the nurses in the clinic.

If you agree to take part a copy of this information sheet will be kept with you, and you will be asked to sign a consent form. If you wish, your GP will be informed of your decision. If you do not wish for your GP to be informed you can still take part in this study. We thank you for your participation.

.**How will we use information about you?**

Research Study Title: Understanding disorders of ovulation in women with polycystic ovary syndrome (PCOS): investigating the action of insulin on granulosa cells.

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Imperial College London is the sponsor for this study and will act as the Data Controller for this study. This means that we are responsible for looking after your information and using it appropriately. Imperial College London will keep your personal data for:

- 10 years after the study has finished in relation to data subject consent forms.
- 10 years after the study has completed in relation to primary research data.

The study is expected to finish in February 2024

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

We will need to use information from your medical records for this research project. This information will include your hospital identification number and date of birth
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. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

As a university we use personally-identifiable information to conduct research to improve health care and services. As a publicly-funded organisation, we have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study. Our legal basis for using your information under the General Data Protection Regulation (GDPR) and the Data Protection Act 2018, is as follows: “performance of a task carried out in the public interest”; Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this

by following the UK Policy Framework for Health and Social Care Research

Where special category personal information is involved (most commonly health data, biometric data and genetic data, racial and ethnic data etc.), Imperial College London relies on "scientific or historical research purposes or statistical purposes"

International transfers

There may be a requirement to transfer information to countries outside the United Kingdom (for example, to a research partner, either within the European Economic Area (EEA) or to other countries outside the EEA. Where this information contains your personal data, Imperial College London will ensure that it is transferred in accordance with data protection legislation. If the data is transferred to a country which is not subject to a UK adequacy decision in respect of its data protection standards, Imperial College London will enter into a data sharing agreement with the recipient research partner that incorporates UK approved standard contractual clauses or utilise another transfer mechanism that safeguards how your personal data is processed.

Sharing your information with others

We will only share your personal data with certain third parties for the purposes referred to in this participant information sheet and by relying on the legal basis for processing your data as set out above.

- Other Imperial College London employees (including staff involved directly with the research study or as part of certain secondary activities which may include support functions, internal audits, ensuring accuracy of contact details etc.), Imperial College London agents, contractors and service providers (for example, suppliers of printing and mailing services, email communication services or web services, or suppliers who help us carry out any of the activities described above). Our third party service providers are required to enter into data processing agreements with us. We only permit them to process your personal data for specified purposes and in accordance with our policies.

The following Research Collaborators that may be involved on the study:

- Imperial College staff only

Potential use of study data for future research

When you agree to take part in a research study, the information collected either as part of the study or in preparation for the study (such as contact details) may, if you consent, be provided to researchers running other research studies at Imperial College London and in other organisations which may be universities or organisations involved in research in this country or abroad. Your information will only be used to conduct research in accordance with legislation including the GDPR and the UK Policy Framework for Health and Social Care Research.

This information will not identify you and will not be combined with other information in a way that could identify you, used against you or used to make decisions about you.

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. This is because some research using your data may have already taken place and this cannot be undone.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you if this could affect the wider study or the accuracy of data collected.

We may also use the your non-identifyable / anonymised data for future research.

Where can you find out more about how your information is used

You can find out more about how we use your information

- by asking one of the research team
- by sending an email to Professor S Franks (s.franks@imperial.ac.uk)
- by ringing us on 0207 594 2109

Complaint

If you wish to raise a complaint about how we have handled your personal data, please contact the research team first by sending an email to Professor S Franks: s.franks@imperial.ac.uk or by ringing us on 0207 594 2109

Following our response, if you are not satisfied please contact Imperial College London's/ Data Protection Officer via email at dpo@imperial.ac.uk via telephone on 020 7594 3502 /or via post at Imperial College London, Data Protection Officer, Faculty Building Level 4, London SW7 2AZ

If you remain unsatisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO)- via www.ico.org.uk. Please note the ICO does recommend that you seek to resolve matters with the data controller (us) first before involving them.

What will happen to the results of the research study?

Results of this study have been or will be presented at scientific meetings and submitted fro publication in scientific journals. More information about these presentations can be obtained from Professor Franks by email request (s.franks@imperia.ac.uk)

Who is organising and funding the research?

The Medical Research Council is funding this research. Imperial College London is sponsor for the project

Who has reviewed the study?

This study was given a favourable ethical opinion for conduct in the NHS) by *Hammersmith and Queen Charlotte's & Chelsea Research Ethics Committee (now West London Chelsea Research Ethics Committee)*

Contact for Further Information

Please contact:

Name: Professor S Franks
Telephone:02027 594 2109
Email: s.franks@imperial.ac.uk

A copy of the written information and signed Informed Consent form will be given you to keep.

Thank you for taking part in this study.