Imperial College London

Research Governance and Integrity Team

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NHS Foundation Trust

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Participant Information Sheet
For adolescents and young people providing consent aged 16 and over

Masses in Young People - International Ovarian Tumour Analysis (MY-IOTA) Study

Prospective Validation and Comparison of Simple Rules, Benign Descriptors, and ADNEX Models for Discrimination between Benign and Malignant Adnexal Masses in young girls and adolescents

REC Number: 23/LO/0988
IRAS 329324
V2. 22/12/23

Chief Investigator: Prof Tom Bourne

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being carried out and what it would involve for you. One of our team will go through the information sheet with you and answer any questions you may have.

Talk to others about the study if you wish. Ask us if there is anything that is not clear. If you decide not to take part or to withdraw at any other time without explanation, your future care will not be affected by your decision. Thank you for reading this.

Why have I been invited?

We have invited you to take part in the study because you underwent an ultrasound scan that suggested there was a cyst within or near your ovary/ovaries. We would like you to participate regardless of whether or not you have been booked for an operation.

What is the purpose of the study?

Ovarian cysts are lumps or sacs on the ovary, which broadly fall into four groups:

1. Physiological – in other words, cysts that naturally occur as part of the normal function of the ovary
2. Benign – usually harmless cysts which develop on the ovary
3. Borderline – cysts which have changes which are pre-cancerous. These are very uncommon in young people.
4. Malignant – cysts which are cancerous. These are also very uncommon and account for <1% of all cancers found in children and young people

It's important for us to be able to tell what type of cyst has formed, as we would not want to inappropriately operate on someone when a cyst is harmless and risk removing healthy ovary. Equally, we want to be sure that appropriate treatment is offered if there are any features of a cyst which make us worried it could be borderline or malignant (cancerous or pre-cancerous).

There is a lot of research to guide us on the typical appearances of cysts in adults, however there is much less information available about cysts in children and young people.

We are a group of researchers who are interested in the ways different ovarian cysts look on ultrasound scan. The main things we are looking at are:

- How cysts can look in babies, children and young adults, from birth to 20 years of age
- If we can use the same tools that we use when looking at adult cysts in people aged under 20
- How ovarian cysts in children and young people change over time

There are also some other things we are interested in, including:

- If a computer can learn to look at cysts and help us to correctly diagnose them
- If there are new biomarkers (i.e. blood tests) which can help us to diagnose certain cysts

Do I have to take part?
It is up to you to decide whether you 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.

What will happen to me if I take part?
We would like to monitor the cyst on your ovary in line with national 'best practice' recommendations. This is by routinely following up the cyst with ultrasound scan(s). These would take place at the following times after their first scan:

- 6-8 weeks
- 3 months
- 12 months

We will ask you some basic health information at the time of the scan. This is because the appearances of the pelvic organs change during puberty and during your stage of the menstrual cycle. Some clinical information, such as your height, weight, family history of cancer, allows us to work out your individual risk factors for certain types of cysts.

However, if the cyst resolves or you have an operation to remove it, you would not have to have all of the follow up scans.

Are there other tests as part of the study?
Your treatment will be decided between you and the clinician responsible for your care. It will not be affected by taking part in the study.

If your doctor feels you need any blood tests, we would also ask for results of those tests to be recorded in the study. If blood tests are needed, we would ask for an extra sample to be taken at the **same** time. This is to look for new blood markers which can help to diagnose cysts in the future. In other words, no extra needles will be needed if you do decide to take part. This would be 6ml, or one teaspoon, of blood. People weighing under 20kg will have a smaller amount of blood taken, which will be adjusted according to your body weight. These study blood tests will be stored in a

freezer and analysed at a later date. We will therefore not be able to give you the results of these tests and they will not change your management. However the findings may help us in the future with patients carrying a similar diagnosis. Your other routine test results will be made available to you.

Pseudonymisation involves replacing your identifiable information (i.e. name, date of birth and hospital number) with a specific study ID. We would also like to use black-and-white pseudonymous scan images to help to train a machine to recognise different types of cysts. The routine images taken include video and still images of the cyst. This would not influence your care, but may help to improve future care if artificial intelligence can be used to analyse scan images.

Will I need any other scans?
Your doctor may recommend an MRI. This is not part of the research study but may be recommended as part of your clinical care. Results of the MRI scan would be collected as part of the research study, once again on an pseudonymous basis.

What happens if I need an operation
Depending on your individual case, your team will discuss with you whether surgery is appropriate and the details of this. We would ask your permission to record what happens in your clinical care and, should you undergo an operation, we would look to see what was found at the time as well as the final results. If you require surgery to remove your cyst, we would like to take a sample of the tissue AFTER it has been removed as per routine care, and then freeze this. We would then process the tissue at a later date alongside your stored blood tests. This allows us to match the blood tests with tissue tests, which helps us to validate new blood tests for cancer.

What do I have to do?
You would need to attend follow up ultrasounds at the time points listed above. Any additional appointments or scans would be guided by your individual case as per your clinician.

If you need a blood test, we would ask to take an additional blood sample at the same time as routine tests (1 teaspoons, 6ml).

If you need an operation, we would take a small sample of the cyst after it has been removed as per standard surgical care and store this tissue sample for future analysis..

What are the alternatives for diagnosis or treatment?
Ultrasound is the routine technique for looking at ovarian cysts. Your treatment and choice of diagnostic test will not be affected by taking part in this study. Your doctor will recommend ongoing care based on your unique case; again, this will not be affected by partaking in the study.

What are the possible disadvantages and risks of taking part?
We are not aware of any risks related to taking part in this study. All participants will have the same management as is currently recommended in the UK after the initial ultrasound scan. No separate blood tests or visits are required, just an extra sample at the same time as your routine tests. There is therefore no additional 'risk' posed by the study blood tests. No additional tissue samples would be taken if you require an operation, only a sample is taken from the cyst after it has been removed.

If we happen to diagnose any other medical conditions whilst you take part in the study, we will inform your GP so that you can receive appropriate ongoing care. Your GP receives scan reports

as part of routine clinical care. The blood and tissue tests (if applicable) will not be processed at the same time and therefore will not provide additional clinical information relevant to your current care.

What are the possible benefits of taking part?
We cannot promise the study will bring you any additional benefit above the care you would normally receive. However, we hope that the information we get from this study will help improve the treatment of children and young people with ovarian cysts in the future.

If a problem is detected, we will refer you appropriately and the condition will be followed-up and managed according to standard practice and guidelines. We will still follow up what happens in your clinical care. We can reassure you that your routine care will not be compromised or altered.

What happens when the research study stops?
There is currently no fixed timespan to follow up ovarian cysts in childhood. Therefore, your follow-up period will be determined by your clinicians. As researchers, we only want your permission to use the results of your follow-up for 12 months after your first scan.

What will happen to the results of the research study?
The study is going to be performed over 2 years. After this time, we will look at the outcomes of the study and this will be shared with the scientific community in the form of a scientific research paper and/or (inter)national presentation. The study results will also be available to you if you wish you receive a copy of the final research paper. No personal identifiable information will be published.

Who is organising and funding the research?
This research project is sponsored by Imperial College London and there is no commercial partner involved in this scientific/academic trial. There is no conflict of interest declared in the study protocol. Health care professionals involved in your care are not paid for including you in the study.

Who has reviewed the study?
All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given a favourable opinion by City and East Research Ethics Committee 23/LO/0988.

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 will 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 the Investigator (Professor Tom Bourne, t.bourne@imperial.ac.uk). The normal National Health Service mechanisms are also available to you. If you are still not satisfied with the response, you may contact the Imperial College, Research Governance and Integrity Team'.

In the rare event that you lose capacity (e.g. due to illness), tissue samples and data already collected may be retained in its pseudonymised form and used in the research. We may continue to use it confidentially in connection with the purposes of this study. This could include further research

after the current project has ended provided that you have provided consent for this. We rely on such consent following loss of capacity, and so approval will not be required under either the Mental Capacity Act 2005 (in England and Wales), the Adults with Incapacity (Scotland) Act 2000 nor the Mental Capacity Act (Northern Ireland) 2016.

We will store your contact details if you indicate that you would like to be informed of the study results on your consent form. You will also have the opportunity to indicate if you consent to your tissue samples to be used for future ethically approved research.

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 December / 2026

For more information / confirmation regarding the end date please contact the study team, see '**WHERE CAN YOU FIND OUT MORE ABOUT HOW YOUR INFORMATION IS USED'** for contact information.

We will need to use information from you and your medical records for this research project.
This information will include your initials, hospital number and date of birth.

People within the College and study team (see section sharing your information with others) will use this information to do the research or to check your records to make sure that research is being done properly and the information held (such as contact details) is accurate. 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.

We will keep all information about you safe and secure. Some of your information will be sent to Belgium for the purposes of data analysis. They must follow our rules about keeping your information safe.

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:

Imperial College London - "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 / Partners in the study
  - Third Party University – KU Leuven, Belgium, for the purposes of statistical analysis of the data

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.

COMMERCIALISATION

Data or samples from the study may also be provided to organisations not named in this participant information sheet, e.g. commercial organisations or non-commercial organisations for the purposes of undertaking the current study, future research studies or commercial purposes such as development by a company of a new test, product or treatment. We will ensure your name and any

identifying details will NOT be given to these third parties, instead you will be identified by a unique study number with any sample / data analysis having the potential to generate 'personal data'.

Aggregated (combined) or anonymised data sets (all identifying information is removed) may also be created using your data (in a way which does not identify you individually) and be used for such research or commercial purposes where the purposes align to relevant legislation (including the GDPR) and wider aims of the study. Your data will not be shared with a commercial organisation for marketing purposes.

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 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.
- 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.

WHERE CAN YOU FIND OUT MORE ABOUT HOW YOUR INFORMATION IS USED

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team
- by sending an email to t.bourne@imperial.ac.uk, or
- by ringing us on 0208 383 5131

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 t.bourne@imperial.ac.uk, or by ringing us on 0208 383 5131

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 and/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.

Who is organising and funding the research?

Essential study expenses are provided by Genesis Research Trust at Imperial College London. Your doctor is not paid for this study.

Who has reviewed the study?

This study was given a favourable ethical opinion for conduct in the NHS (or private sector) by City and East REC.

Contact for Further Information

If you want more information, before or after you return your form, you can phone:

Ms Jemma Johns and Dr Oyin Alabi on 07890251949

Email: kch-tr.womenshealthresearch@nhs.net

King's College Hospital:

Ms Jemma Johns and Dr Oyin Alabi are based at:
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