Imperial College Healthcare NHS Trust

Participant Information Sheet

Study Title: Bladder Cytokines and Inflammation

Information for patients, relative and carers

Version 1 27/11/2024

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish.

What is the purpose of the study?

Currently there is a poor understanding of the underlying cause and the biological changes that occur to cause urinary symptoms such as: long-standing bladder pain, urinary urgency, and incontinence. Symptoms often overlap and change over time and recurrent infection in the bladder can also alter these.

We do often see that the bladder appears inflamed and previous research has shown that inflammation inside the bladder may cause many urinary symptoms. The purpose of this study is to understand what sort of inflammation may underlay which bladder symptoms. This could lead to new treatment targets in the future.

Why have I been chosen?

You are eligible to take part because you have: 1) urinary symptoms which have lasted for more than 3months and 2) you are already undergoing a cystoscopy and bladder biopsy procedure as part of your routine NHS care.

Imperial College Healthcare NHS Trust

Do I have to take part?

No – participation is completely voluntary and whether you take part or not- will not affect your medical care in the NHS.

What will happen to me if I take part?

If you would like to take part:

- We ask you to sign a consent form for research participation
- You are asked to fill out three short questionnaires about your symptoms
- A urine sample is taken whilst you are asleep, and an extra bladder biopsy is taken (you are having two on the NHS – so this is an extra tissue sample for research)

What are the possible disadvantages and risks of taking part?

As an extra tissue sample is taken this very slightly increases the risk of bleeding or damage to the bladder. This risk is uncommon for a cystoscopy procedure.

What are the possible benefits of taking part?

There is a potential that taking part in this research could find new therapeutic targets for management of your symptoms- but this benefit would be in the longer term. In the short term there is likely no benefit to taking part.

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 (Insert name and contact details). 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'.

How will we use information about you?

Imperial College Healthcare NHS Trust 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 Healthcare NHS Trust will keep your personal data for:

- 5 years after the study has finished in relation to data subject consent forms

All other data kept is anonymised into the research database.

We will need to use information from your electronic medical records for this research project. This information will include:

- Your name
- Date of birth
- Hospital number and NHS number

These are included on your consent form for research. Following this any additional information is anonymised onto the research database.

People within the Trust and study team 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.

We will keep all information about you safe and secure.

Imperial College Healthcare NHS Trust

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/NHS Trust 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/Imperial College Healthcare NHS Trust - "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

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 Healthcare NHS Trust 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/Imperial College Healthcare NHS Trust 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.

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.

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/
- or emailing the Data Protection Officer: imperial.dpo@nhs.net
- telephone: 020 3311 7344

Enquiries relating to Subject Access Requests (DPA) should be sent to: Imperial.accesshealthrecords@nhs.net

Complaints

If you wish to raise a complaint about any part of your participation in this research project, then please contact the research team first- by contacting the gynaecology department and then asking to the query to be taken to Dr Bernadette Lemmon.

Following our response, if you are not satisfied please contact Imperial College London's/Imperial College Healthcare NHS Trust's Data Protection Officer via email at dpo@imperial.ac.uk / imperial.dpo@nhs.net via telephone on 020 7594 3502 / 020331304001 and/or via post at Imperial College London, Data Protection Officer, Faculty Building Level 4, London SW7 2AZ./8th Floor of Salton House, ICT Division, St Mary's Hospital, Praed Street, London, W2 1NY

NHS
Imperial College Healthcare
NHS Trust

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 will be submitted for publication in peer reviewed journals. Results may also be presented at International Conferences. This study has also been submitted to the ISRCTN registry which means that a summary of the project results will be available online. This project is part of a further research degree- and MD (res) which will be presented and submitted to Imperial College London.

There will never be any identifiable personal data ever published or presented from participation in this project.

Who is organising and funding the research?

This research project has been designed, set-up, and conducted byyy the urogynaecology department at St Mary's Hospital, Imperial College Healthcare Trust under Professor Khullar. This project has been awarded a research grant by The British Society of Urogynaecology (BSUG).
No members of this research team are being paid for conducting this research.

Who has reviewed the study?

This study has been approved by the Imperial College Tissue and Biobank which is regularly reviewed by the Research and Ethics Authorities of England and Wales (REC Wales 3). This project has individually sought approval from the Health Research Authority and Research Ethics Committee review.