

PATIENT INFORMATION SHEET

1. Study title

Inclusion of patients with Klinefelter's syndrome (KS) in the national KS RedCap database

2. Invitation paragraph

You are being invited to take part in research and long-term monitoring of KS. Before you decide it is important for you to understand why this is being done and what it will involve. Please take time to read the following information carefully. 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.

Thank you for reading this.

3. What is the purpose of the study?

The national-access Klinefelter Syndrome Multidisciplinary Team clinic is based at the Rare Disease Centre at St Thomas Hospital, encompassing 8 specialties. We see patients with multisystem disease secondary to this genetic condition. However, long term data on the natural history of the disease is still lacking, especially with regards to risk of thromboembolism, effects of Testosterone therapy, fertility outcomes and risk of osteoporosis, diabetes and cancers – all issues linked to Klinefelter patient care. We have secured funding from the Klinefelter Association (KSA) to develop a secure database for our patients seen in the KS MDT clinic in order to help monitor long term patient reported outcomes.

4. Why have I been chosen?

You have been chosen as you have a diagnosis of Klinefelter's syndrome.

5. Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to participate 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 from the study at any time and without giving a reason. This will not affect the standard of care you receive.

6. What do I have to do if I decide to take part?

If you decide to take part in this study you will be asked to complete a questionnaire which we will send to you every 6 months.

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

There are no expected risks of taking part.

8. What are the possible benefits of taking part?

We hope that the information we collect from this study will help to inform the management of KS. For example, this could include guidelines for future care of XXY/KS men

9. Will my taking part in this study be kept confidential?

The answers you submit will be confidential. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information at <https://www.guysandstthomas.nhs.uk/terms-conditions/disclaimer.aspx>

The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details. Any information about you which leaves the hospital/surgery will have your name and address removed so that you cannot be recognised from it.

10. What will happen to the results of the research study?

The results of the study will be published in recognised journals. This will make the results available to all other researchers interested in this field. You will not be identified in any publication.

If you consent to be contacted in the future about the results of this study, you will receive a summary of the findings by post or email once the study is over.

11. Who is organising and funding the research?

The ongoing research is not funded by an organisation or NHS trust. The setting up of the database is partly funded by support from the Klinefelter Association (KSA).

12. Who has reviewed this study?

This study has been reviewed by the staff of the Department of Urology at Guy's and St Thomas' NHS Trust.

13. Contact for Further Information

You will be given a copy of the information sheet and a signed consent form to keep. You may withdraw from the study at any time without affecting your treatment.

Thank you for taking time to read this information sheet, please do not hesitate to contact us if you have any queries or need any further information.

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