Patient Information Sheet

Total Or Partial Knee Arthroplasty Trial

You are being invited to participate in a research study. Before you decide whether to participate or not 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 to decide whether or not you wish to take part.

1. What is the purpose of this study?

Disease of the medial part of the knee is very common. Surgery to help reduce pain and stiffness is a recognised means of treatment. There are two ways to do this operation. One is to replace the whole knee with a Total Knee Replacement. The other way involves only replacing the area which is affected with a Partial Knee Replacement. This study was designed to assess the best way to treat medial knee disease in terms of recovery for patients and the costs involved.

2. Why have I been chosen?

You have been chosen because you have been diagnosed with osteoarthritis of the medial part of the knee.

3. Do I have to take part?

It is up to you to decide whether or not to take part. You are free to withdraw at any time and without giving a reason.

4. What will happen if I take part?

Sometimes the surgeon cannot tell which type of replacement knee would be best for a patient. To learn more, we need to make comparisons between different treatments. To do this we will randomly put you into a treatment group. In this case there are two groups, one group will have a total knee replacement inserted and one will have a partial knee replacement inserted.

Both are suitable implants for your condition.

Partial knee replacement is considered a bit more specialised than the total replacement and not all surgeons will perform this operation. If your surgeon does not perform a partial knee replacement they may refer you onto their colleague at the same hospital who does. You will receive their usual standard of care and your surgery will proceed as normal.

After that TOPKAT aims to follow your case for 5 years after your knee replacement surgery. The follow up regime will consist of;

- Postal Questionnaires containing relevant questions about your knee. These will be sent to your home for you to complete and return to the central study office in Oxford/Aberdeen.

- Xrays of your knee which will be conducted at your local hospital and will be arranged by the research team there.

- Clinical assessments of your knee to check function and strength. These will also be conducted at your local hospital by the research team there.

Assessments will be performed at 2 months, and then yearly after your operation until 5 years. The assessment at 2 months, 1 year and 5 years will involve clinical assessment, the others are postal questionnaires. If the study continues you may be asked to provide information at 7 and 10 years after your operation.

Xray appointments and the clinical examinations will take about 45 minutes each. All attempts will be made to make these visits as convenient for you as possible. The local research team works in collaboration with your surgeon and he/she may often see you during these visits.

5. Expenses and payments

Travel to your local hospital for the follow up appointments will be reimbursed.

6. Is there an alternative treatment?

Once you have completed conservative treatment for your knee problems (eg: physiotherapy), the main treatment options are the two types of surgery described above.

7. What are the possible risks of taking part?

There are no anticipated risks or disadvantages to participating in TOPKAT. Whichever type of treatment you are allocated to, your operation will be performed by a competent and trained surgeon. There are risks associated with all surgery and anaesthetics. Steps are always taken to ensure that these risks are minimised. As part of routine care, you will be well informed of potential risks.

Xrays always pose risks of radiation exposure. However, the amount of exposure involved in the TOPKAT study is minimal and is within recommended guidelines. Some of the xrays required for TOPKAT are performed routinely. Only two further xrays are required. These are necessary to examine how the new knee looks and if the disease is still present in the joint.

8. What are the possible benefits of taking part?

Your knee condition will be managed by well practiced and widely recognised means. The information we get from this study will help improve the future treatment of people with diseases of the medial part of the knee. During the follow up visits you will have one-on-one sessions with an experienced clinical researcher who may be able to help with any knee related problems you are having.

9. What happens when the research stops?

When the study finishes, it may be over 10 years since you had your operation. Any knee related care you require beyond this time should be arranged in the usual way via your GP.

10. What if there is a problem?

Complaints If you wish to complain formally, you can do this through the NHS Complaints Procedure, (details can be obtained from your hospital) or you can find further information on ethics in research on the National Research Ethics Service website **(www.nres.npsa.nhs.uk).**

Harm NHS indemnity operates in respect of the clinical treatment with which you are provided. In addition, the University of Oxford has appropriate insurance-related arrangements in place in respect of the University's role as Research Sponsor of this study.

11. Will my taking part be kept confidential?

All patient information is stored on password protected computer databases or in locked filing cabinets. You will be allocated a study number and staff not directly involved with your care will know you only by this number. When the results of the study are reported, individuals who have taken part will not be identified in any way.

12. What if relevant new information becomes available?

Any new information about the two types of knee replacement will be considered in relation to its effect on patient care. If such information proves the study related treatments to be harmful to patients, the study will stop. If this happens, the research team will contact you to discuss the situation further.

13. What if I change my mind about taking part?
If you decide to withdraw from the study, your standard of care will not be affected. You will still be asked to attend the usual follow-up clinics required by your surgeon and hospital. These will not be part of the study.

14. Will my GP be informed of my involvement in the study?
With your consent your GP will be notified of your participation in the TOPKAT study.

15. How will the information I provide be used?
At the end of the study patients who participated will be offered a report detailing the study's findings. This will be made available on the study website also. We plan to publish the results in a health journal so others can read about and learn from the results of the study.

16. Who is organising and funding the research?
This nationwide trial is being funded through the National Institute of Health's Health Technology Assessment (HTA) Programme, which is part of the Department of Health. You can access information about them on the HTA website (**www.hta.nhs.uk**).

The Nuffield Department of Orthopaedic, Rheumatology & Musculoskeletal sciences (**www.ndorms.ox.ac.uk**) a department of the University of Oxford, in Oxford will undertake the day to day running of the trial, under the supervision of Dr David Beard and Professor David Murray. The University of Oxford will act as a sponsor for the study and will be responsible for the governance of the trial.

The Centre for Healthcare and Randomised Trials (CHaRT), Health Services Research Unit in the University of Aberdeen (**www.charttrials.abdn.ac.uk**) in Aberdeen will be responsible for collecting and monitoring the information generated.

17. Who has reviewed this study?

A Research Ethics Committee, the UK Comprehensive Research Network, each hospital's Research and Development Committee/Department and your local Orthopaedic Consultant have reviewed this study

18. Further Information

If you require more information about this study please call one of the telephone numbers provided to speak to a clinical member of the research team or, alternatively look at the study website **https://viis.abdn.ac.uk/HSRU/topkat/**. Your surgeon and GP may also be able to provide you with further information.

Thank you for reading this and considering taking part in this study.

If you have any questions or would like any more information please contact the

TOPKAT Study Office by phone: 01865 737210

Or email topkat@ndorms.ox.ac.uk

Please keep this information sheet for your records.

If you agree to enter the study, please sign theconsent form and we will return a copy to you.