Cemented Versus Cementless Unicompartmental Knee Arthroplasty (UKA) - A Single-blind Randomised Controlled Trial

Clinicaltrials.gov ID: NCT05935878

Direct Line: Oxford (01865)
Switchboard: (01865) 741155
Fax: (01865) 742348

NUFFIELD ORTHOPAEDIC CENTRE
Windmill Road, Headington, Oxford OX3 7LD

Our ref:

Your ref:

OxREC No.: C02.101

20th May 2002
Version 1

CEMENTED VERSUS CEMENTLESS UNICOMPARTMENTAL KNEE REPLACEMENT (UKR) – A SINGLE BLIND RANDOMISED CONTROLLED TRIAL.

Invitation paragraph

"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 friends, relatives and your GP 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".

Thank you for reading this.

What is the purpose of the study?

Unicompartmental knee replacement for selected cases of osteoarthritis is less invasive than total knee replacement. It gives better range of movement; patients stay for shorter time in the hospital and have a more natural feel than total knee replacement. Usually, the implant is fixed in the bone using bone cement. However, there are potential disadvantages of using bone cement. The operation takes longer; cement can get squeezed out into the surrounding tissues and may interfere with function. To avoid these problems, the implant can be fixed without cement. Cementless components have a special coating to encourage bone in-growth and fixation. Although we believe cementless fixation will be at least as good as cemented fixation, there is a risk that it could be worse and might result in loosening.

The aim of this study is to compare cemented UKR with cementless UKR. The study will be carried out over a period of two years.

Why have I been chosen?

All the patients listed for undergoing UKR have been invited to take part in this study. A total of 50 patients – 20 in the group of cemented UKR and 30 in the group of cementless UKR will participate in this study.

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 would 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. This would not affect the standard of care you receive.'

What would happen to me if I take part?

If you decide to take part in this study, you will be given a copy of this information sheet and a signed consent form to keep.

This study is a randomised trial. Sometimes because we do not know the best way of treating participants, we need to make comparisons. People will be put into groups and then compared. The groups are selected by a computer, which has no information about the individual – i.e. by chance. Participants in each group then have a different treatment and these are compared.

The chance they have of getting the study treatment i.e. cementless Unicompartmental knee replacement is one in two.

There are two components of an UKR, which are attached to the bone. These are called the femoral component which is attached to the thigh bone (femur) and the tibial component, which is attached to the shin bone (Tibia). Prior to starting the randomised trial, five patients will have a cementless tibia implanted with a cemented femur and five patients will have a cementless femur implanted with cemented tibia.

If you decide to take part in the study, you would randomly be allocated to either the cemented or cementless UKA group. Both the types of implants have similar surgical technique. At the time of operation, special marker balls (less than 1 mm in diameter) will be placed in the bone surrounding the prosthesis to allow investigation of the position of the implant in relation to the bone with the help of X-rays. These marker balls have been widely used without any side effects.

After the operation, you will be seen in the follow up clinics. There are no extra visits as compared to standard protocol. The follow up visit will last for about an hour. It will involve assessment by a doctor and special x-rays at 6 months, 12 months and 2 years after the operation to see the position of the prosthesis. We use as low a dose of X-rays as possible to minimise any side effects.

What would I have to do?

There are no specific lifestyle or dietary restrictions after the operation. After either type of operation, we ask the patient to avoid high impact sports like squash, basketball and football. If you are on any regular medication, you can continue to take them. You need not refrain from giving blood if you wish to do so. What happens if the participant becomes pregnant?

What is the drug or procedure that is being tested?

This study is testing the cementless Unicompartmental knee replacement. In selected cases of osteoarthritis, UKA has been proven to give satisfactory long-term results. However, there are certain potential disadvantages of using bone cement as outlined earlier. To overcome these possible disadvantages, a new cementless implant has been developed. As the name suggests, it does not need use of cement for fixation in the bone. This implant has a special coating of hydroxyapatite. This

coating helps the implant to get fixed into the bone by encouraging new bone formation and bone in-growth.

What are the alternatives for diagnosis or treatment?

Obviously, there are other ways of treating the arthritis. Total knee replacement, which means changing the whole knee joint to a prosthetic one, is one such possibility.

What are the side effects of taking part?

As far as we are aware, there are no side effects of using this implant. If you suffer from any unusual symptoms after the operation, you should report them next time you meet with the researcher. If you become concerned at any time, you can contact Dr. Hemant Pandit on 01865 227457. If you wish to contact somebody out of hours, you may contact the Nuffield Orthopaedic Centre on 01865 741155 and ask to speak to the registrar on call.

What are the possible disadvantages and risks of taking part?

With both the cemented and cementless UKR, there is a small chance that the component may become loose or bone supporting the component may break. It is possible that the chance of complication occurring with cementless component is higher than with cemented component. As with any other operation, there are risks of anaesthesia, risk of infection and risk of developing a clot in the leg. We take all necessary precautions to minimise the incidence of any of these complications.

If you have private medical insurance, you should check with the company before agreeing to take part in the trial. You need to do this to ensure that their participation will not affect your medical insurance.

Every patient before an operation, undergoes tests to make sure he does not suffer from conditions like diabetes or high blood pressure. If we find a condition of which you were unaware, we will treat it accordingly after making you aware of the condition.

What are the possible benefits of taking part?

'We believe that both the cemented and cementless UKR will help you. There is a chance that some of the problems that occasionally occur with cement will be avoided with the cementless fixation. If this is the case, the study should identify this and thus will help other patients in the future.

What if new information becomes available?

'Sometimes during the course of a research project, new information becomes available about the treatment/drug that is being studied. If this happens, your research doctor will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw your research doctor will make arrangements for your care to continue. If you decide to continue in the study you will be asked to sign an updated consent form. Also, on receiving new information your research doctor might consider it to be in your best interests to withdraw you from the study. He/she will explain the reasons and arrange for your care to continue.'

What happens when the research study stops?

We expect that UKR will continue to function well whether it is cemented or cementless.

What if something goes wrong?

'If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it. Regardless of this, if you wish to complain about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms may be available to you.'

Would my taking part in this study be kept confidential?

'All information which is collected about you during the course of the research would be kept strictly confidential. Any information about you, which leaves the hospital, would have your name and address removed so that you cannot be recognised from it. We will inform your GP about your participation in this study. Other doctors treating you but not involved in this research will also be informed if necessary.

What would happen to the results of the research study?

You should be able to tell the participants what will happen to the results of the research. When are the results likely to be published? Where can they obtain a copy of the published results? Will they be told which arm of the study they were in? You might add that they will not be identified in any report/publication.

Who is organising and funding the research?

This research is being organised by Nuffield Orthopaedic Centre. One or more doctors conducting the research are being paid for including and looking after the participants in the study.

Who has reviewed the study?

The Oxfordshire Clinical Research Ethics Committee has reviewed this study.

Contact for Further Information

If you need more information, you can contact us on 01865 227457.

Thank you for reading this information sheet.

Professor David Murray
Consultant Orthopaedic Surgeon – Nuffield Orthopaedic Centre, Oxford.

Direct Line: Oxford (01865)
Switchboard: (01865) 741155
Fax: (01865) 742348

NUFFIELD ORTHOPAEDIC CENTRE
Windmill Road, Headington, Oxford OX3 7LD

Our ref:

Your ref:

Title of Project **Cemented Versus Cementless Unicompartmental Knee Arthroplasty (UKA) – A single-blind randomised controlled trial.**

OxREC NO.: C02.101 **Version 1, Date: 20/5/2002**

Have you read the Invitation Letter/Information sheet? Yes/No
Have you had an opportunity to ask questions and discuss this study? Yes/No
Have you received satisfactory answers to your questions? Yes/No
Have you received enough information about the study? Yes/No
Who have you spoken to? Dr/Mr/Ms

Do you understand that you are free to leave the study:
- at any time,
- without having to give a reason for leaving and without affecting your medical care?

Yes/No

Signed: _____

Date: _____

Name (in block letters):. _____

Signature of Investigator : _____

Name (in block letters)