



# **PATIENT INFORMATION LEAFLET**

**The KORAL study is funded by the UK NHS R&D Health  
Technology Assessment Programme**

## **What is osteoarthritis of the knee?**

Osteoarthritis (OA) is a disease that affects the joints in the body. 'Osteo' means bone and 'arthritis' means joint damage and swelling (inflammation). When joints are swollen and damaged they can be painful and can affect mobility. Osteoarthritis of the knee is a very common form of osteoarthritis.

## **How can osteoarthritis of the knee be treated?**

There are a range of treatments available for people have OA of the knee. These include painkillers (such as paracetamol), anti-inflammatory drugs or creams, steroid injections, and surgery. Sometimes, 'keyhole' surgery techniques are used to 'wash out' loose fragments of bone and other tissue from the joint. This is called arthroscopic lavage. Sometimes, during a lavage, additional procedures may be carried out – such as smoothing the surfaces of the joint, removing flaps of damaged hard cartilage, or trimming of torn soft cartilage. This is called debridement. These techniques may offer pain relief in the early stages of OA, but previous studies do not tell us if these surgery techniques really work.

## **Introduction to the study**

You are being invited to take part in a research study that aims to find out if arthroscopic lavage for osteoarthritis really works. 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 enclosed information carefully and discuss it with your family, friends or General Practitioner if you wish. Do not hesitate to contact us if there is anything you do not understand or if you would like more information. Please take time to decide whether or not you wish to take part.

## **What is the purpose of the study?**

The purpose of this study is to find out if arthroscopic lavage or debridement is an effective treatment for people with OA of the knee. In this study, doctors, researchers and patient representatives are working together to compare three options against each other:

- 'arthroscopic lavage'
- 'placebo' procedure (simulated surgery)
- Management without surgery (e.g. physiotherapy).

## **What treatment will I receive?**

If you agree to take part in the study, your type of treatment will be chosen randomly by a computer. You will not know which treatment group you are in if you are allocated to receive either 'arthroscopic lavage' or the 'placebo' procedure (simulated surgery). You will have a one in three chance of receiving either:

### **1. Arthroscopic lavage**

If you are allocated to this group you will receive arthroscopic lavage (with some debridement if your surgeon thinks it is necessary). Arthroscopic lavage is a 'keyhole' surgery technique. A small camera will be inserted into your knee to allow the surgeon to see. The surgeon will then 'wash out' any loose fragments of bone and other tissue from the joint. Debridement involves smoothing the surfaces of the joint, removing any flaps of damaged hard cartilage, and trimming torn soft cartilage. This procedure would not usually require an overnight stay in hospital but approximately 2 to 3 days off work (depending on nature of work). This procedure requires a general anaesthetic.

## **2. 'Placebo' procedure (simulated surgery)**

If you are allocated to this group you will receive a 'placebo' procedure. Placebo, or dummy, tablets are regularly used in studies to evaluate new medicines. This study will use a surgical placebo. Placebo surgery simulates or mimics a surgical procedure, but the person allocated to receive it does not actually undergo the full surgical procedure.

If you are allocated to this group, your surgeon will make three very small incisions in the skin on your knee. No instrument would be inserted into your knee. These incisions would be very similar to the ones given to people in the 'arthroscopic lavage' group, but they would not be as deep. This procedure would not usually require an overnight stay in hospital but approximately 2 to 3 days off work (depending on nature of work). This procedure requires a general anaesthetic.

## **3. Management without surgery**

If you are allocated to this group, you will not receive any surgery. Instead, the surgeon responsible for your care will recommend the standard form of treatment such as, for example, physiotherapy.

### **What will I be asked to do if I take part?**

If you agree to take part in this study you will be randomly allocated to receive one of the three treatments. The treatment will be given by the same doctors and nurses who would treat you if you were not taking part. You will then be followed-up at 6, 12 and 24 months. You will sent a questionnaire which will ask about any pain in your knee, your general health and any visits you have had to the GP or hospital about your knee arthritis.

### **Why have I been approached?**

This hospital is one of several centres throughout the UK taking part in this study. As a person currently receiving care for OA of the knee, you may be eligible to take part in the study. We plan to involve about 500 patients who have OA of the knee throughout the UK.

### **What are the advantages and disadvantages of taking part?**

#### *Advantages*

The treatments, including the placebo procedure, may offer some relief from the painful symptoms of early OA of the knee. A similar study carried out on a small scale in the US has found that all treatments offered some benefit (Moseley 2002). The information we get from this study may help us to provide better treatment in the future for patients with OA of the knee.

#### *Disadvantages*

The disadvantages of either surgical operation (arthroscopic lavage or the placebo procedure) are:

- it requires approximately 2 to 3 days off work (depending on nature of work)
- as with all surgery that involves a general anaesthetic, there is a risk, albeit a very low risk, of serious complications or operative death.

### **We want to reassure you that:**

- Your involvement in the study is entirely voluntary.
- You are free to withdraw at any time and this would not affect your current or future medical treatment. Although we do not expect participation to affect private medical insurance, if you have insurance, please check with the company before agreeing to take part in the study.
- All information collected for the study will be treated as confidential and used only for the purpose of the study.
- We will inform your GP that you are taking part.
- All people taking part will be kept informed about the study and will be sent a summary of the results. The results of the study will be published in medical journals. Participants will not be identifiable in any of the study reports.
- This study has been approved by all the appropriate agencies.
- This study is being undertaken on behalf of the NHS.
- This study is being developed with full collaboration of Arthritis Care.

**What if something goes wrong?**

In the very unlikely event that you are harmed by taking part in this study, there are special insurance arrangements being put in place.

**Who is organising and funding the research?**

The study is funded by the Department of Health Research and Development Health Technology Assessment Programme. A team based in Aberdeen is responsible for the day to day management of the study. However, this hospital is one of several throughout the UK taking part and your doctor is part of the collaborating team.

**Thank you for reading this**

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