Part 1

KORAL

KNEE OSTEOARTHRITIS:
ROLE OF ARTHROSCOPIC LAVAGE

Part 1:
Why is this study being conducted?

PATIENT INFORMATION LEAFLET
PHASE 2: PILOT STUDY

Version 3, January 2007
ISRCTN02328576

We would like to invite you to take part in a research study. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Talk to others about the study if you wish. Part 1 tells you the purpose of this study. Part 2 gives you more detailed information about what would happen if you took part. Please 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.

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

Osteoarthritis (OA) is a disease that affects the joints in the body. When joints are swollen and damaged they can be painful and can affect mobility. Osteoarthritis of the knee is a very common form of the disease. There are a number of treatments available for people who have OA of the knee. These include painkillers (such as paracetamol), anti-inflammatory drugs or creams, steroid injections, physiotherapy 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, additional procedures may be carried out – such as smoothing the surfaces of the joint, removing flaps of damaged hard cartilage, and trimming torn soft cartilage. This is called **debridement**. These surgical techniques may offer pain relief in the early stages of OA, but doctors and researchers are not sure if these surgical techniques are very effective.

"Clinical trials" are a recognised way of finding out if treatments are effective. The NHS is keen to run a clinical trial to find out if arthroscopic lavage (with or without debridement) is effective. One option that has been suggested is a trial that would compare 'arthroscopic lavage,' against a 'placebo' procedure (simulated surgery). Placebo surgery simulates or mimics a surgical procedure, but the person does not actually undergo the full surgical procedure. The NHS has funded a national team of researchers to explore whether such a trial could be undertaken. In order to be successful, such a trial would need a large number of people to agree to take part. We have already had extensive discussions with surgeons, anaesthetists and other people like you who have knee osteoarthritis to help us decide what the trial might look like.

Why have I been approached?

Your hospital is taking part in this pilot study. As a person currently receiving care for OA of the knee, you may be eligible to take part in the study.

Do I have to take part?

It is up to you to decide whether or not to take part. We will describe the study to you, go through this information sheet and answer any questions you may have. You will be given a copy of this information sheet to keep. If you are eligible and agree to take part, we will then ask you to sign a consent form. If you decide not to take part, this will not affect the standard of care you receive. You do not have to give a reason if you decide not to take part, but as this is a pilot study, it would be very helpful for researchers to know your reasons why.

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

If you agree to take part in this pilot study you will receive one of three procedures: 1) Arthroscopic lavage; 2) Simulated arthroscopic lavage ('placebo' procedure); or 3) Specialist re-assessment and non-surgical management (eg drugs or creams, physiotherapy or steroid injections).

Your procedure will be chosen 'randomly' by a computer. You will not know which group you are in if you are allocated to receive either 'arthroscopic lavage' or simulated arthroscopic lavage (the 'placebo' procedure). 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 2, 6, 12 and 24 months. We will send you a questionnaire from the KORAL study office in Aberdeen asking about any pain in your knee, your general health and any visits you have had to the GP or hospital about your knee arthritis.

What will happen to me if I take part?

If you agree to take part, you have a one in three chance of receiving one of the following three procedures:

1. **Arthroscopic lavage**
   Arthroscopic lavage is a 'keyhole' surgery technique. Three incisions will be made in your knee. 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. If necessary, the surgeon will also carry out 'debridement', which 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 usually requires approximately 2 to 3 days off work (depending on the nature of your work). ***This procedure requires a general anaesthetic.***

2. **'Simulated' arthroscopic lavage ('placebo' procedure)**
   This study will use a surgical placebo. Placebo surgery simulates or mimics a surgical procedure, but the person does not actually undergo full arthroscopic lavage. Your surgeon will make three very small incisions in the skin on 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. No instrument will be inserted into your knee. This procedure would not usually require an overnight stay in hospital but usually requires approximately 2 to 3 days off work (depending on the nature of your work). ***This procedure requires a general anaesthetic.***

3. **Specialist re-assessment and non-surgical management (eg drugs or creams, physiotherapy, or steroid injections)**
   If you are allocated to this group, you will not receive any surgery. Instead, you will have a specialist re-assessment of your condition with the consultant surgeon responsible for your care. (S)he might recommend a number of treatments eg physiotherapy or injection depending on your symptoms.

What are the advantages and disadvantages of taking part?

Advantages

The information we get from this study may help us to provide better treatment in the future for patients with osteoarthritis of the knee. However, taking part will not necessarily help your osteoarthritis. The procedures, including the placebo procedure, may offer some relief from the painful symptoms of early OA of the knee. A similar study carried out with a small number of participants in the USA found that all procedures offered some benefit. However, it should be noted that any relief from pain experienced by those allocated to the placebo group will be due to what is known as a 'placebo effect.' This is where people in the placebo group may improve solely because they think they have received an active treatment.

Disadvantages

The disadvantages of taking part are that:

- the 'placebo' procedure is not designed to improve symptoms
- 2 to 3 days off work (depending on nature of your work) are required for surgery
- there is the potential for some post-operative pain with the surgical procedure
- as with all surgery that involves a general anaesthetic, there is a risk, albeit a very low risk, of serious complications or operative death.

What treatment options will be available for me if I decide not to take part?
A decision not to take part in this study will not affect the standard of care you receive. There are a range of treatments available for people who have OA of the knee. Your doctor will discuss the range of treatments available to you in your hospital.

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 if they wish. 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?
Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. Detailed information about this is given in Part 2 of this leaflet.

Will my taking part in the study be kept confidential?
Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in part 2 of this leaflet.

If the information in this leaflet has interested you and you are considering participation, please read the additional information in Part 2 of this leaflet before making any decision.

Thank you for reading this

KORAL STUDY OFFICE
Health Services Research Unit
University of Aberdeen
Foresterhill
Aberdeen, AB25 2ZD
Tel: 01224 554338
Fax: 01224 554580
Email: koral@abdn.ac.uk

Local details

Clinical lead:

Recruitment Officer:

Part 2

KORAL

KNEE OSTEOARTHRITIS:
ROLE OF ARTHROSCOPIC LAVAGE

Part 2:
What will happen if I take part?

PATIENT INFORMATION LEAFLET
PHASE 2: PILOT STUDY

Version 3, January 2007
ISRCTN02328576

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

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

As indicated in part 1 of this patient information leaflet, if you agree to take part in this pilot study you will receive one of three procedures: 1) Arthroscopic lavage; 2) Simulated arthroscopic lavage ('placebo' procedure); or 3) Specialist re-assessment and non-surgical management (eg drugs or creams, physiotherapy or steroid injections).

Your procedure will be chosen 'randomly' by a computer. You will not know which group you are in if you are allocated to receive either 'arthroscopic lavage' or simulated arthroscopic lavage (the 'placebo' procedure). 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 2, 6, 12 and 24 months. We will send you a questionnaire from the KORAL study office in Aberdeen asking about any pain in your knee, your general health and any visits you have had to the GP or hospital about your knee arthritis.

What will happen to me if I take part?

If you agree to take part, you have a one in three chance of receiving one of the following three procedures:

1. **Arthroscopic lavage**

   Arthroscopic lavage is a 'keyhole' surgery technique. Three incisions will be made in your knee. 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. If necessary, the surgeon will also carry out 'debridement', which 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 usually requires approximately 2 to 3 days off work (depending on the nature of your work). ***This procedure requires a general anaesthetic.***

2. **'Simulated' arthroscopic lavage ('placebo' procedure)**

   This study will use a surgical placebo. Placebo surgery simulates or mimics a surgical procedure, but the person does not actually undergo full arthroscopic lavage. Your surgeon will make three very small incisions in the skin on 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. No instrument will be inserted into your knee. This procedure would not usually require an overnight stay in hospital but usually requires approximately 2 to 3 days off work (depending on the nature of your work). ***This procedure requires a general anaesthetic.***

3. **Specialist re-assessment and non-surgical management (eg drugs or creams, physiotherapy, or steroid injections)**

   If you are allocated to this group, you will not receive any surgery. Instead, you will have a specialist re-assessment of your condition with the consultant surgeon responsible for your care. (S)he might recommend a number of treatments eg physiotherapy or injection depending on your symptoms.

What will happen if I don't want to carry on with the study?

You are free to withdraw at any time and this would not affect your current or future medical treatment. The information we already have will be stored securely and confidentially, unless you request that we delete it.

What if something goes wrong?

We do not expect any harm to come to you by taking part in this study. However, 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, or have any concerns 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 (which includes professional indemnity insurance) would be available to you.

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions (KORAL co-ordinating office 01224 554338). If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure (or Private Institution). Details can be obtained from the hospital.

Will my taking part in the study be kept confidential?

All information which is collected about you during the course of the research will be kept strictly confidential, and any information about you which leaves the hospital will have your name and address removed so that you cannot be recognised.

Your name will not be written on any of the follow up questionnaires. The information you give us will be kept secure using passwords. Any information you provide will be seen by the research team only.

Involvement of the General Practitioner/Family doctor (GP)

With your permission, we will inform your GP that you are taking part.

What will happen to the results of the research study?

The results of this pilot study will help us to plan a full-scale trial for the UK. It will help us make sure that the design of the trial is acceptable to surgeons and patients.

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 the University of Aberdeen is responsible for the day-to-day management of the study. However, your hospital is taking part in the study and your doctor is part of the collaborating team.

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given favourable opinion by North West Research Ethics Committee.

What if relevant new information becomes available?

Sometimes we get new information about the procedure being studied. If this happens, your hospital doctor will tell you and discuss whether you should continue in the study. If you decide not to carry on, your hospital doctor will make arrangements for your care to continue. If you decide to continue in the study he may ask you to sign an updated consent form. If this happens, your hospital doctor might consider you should withdraw from the study. He/she will explain the reasons and arrange for your care to continue. If the study is stopped for any other reason, we will tell you and arrange your continuing care.

Further information and contact details
If you would like further information on any aspect of this research please contact the following numbers:

- For general information about research: general information about arthritis can be found on the Arthritis Care website - www.arthritiscare.org.uk/scotland. If you have any queries about research please contact the KORAL Study Office in the Health Services Research Unit at the University of Aberdeen, email koral@abdn.ac.uk, tel 01224 554338.

- For specific information about this research project: please contact the Recruitment Officer, Lynne Swan, email l.e.swan@abdn.ac.uk, tel 01224 554335.

- Who you should approach if unhappy with the study: you can speak to the researchers at the above contact details. If you remain unhappy and wish to complain formally this can be done through the NHS Complaints Procedure.

Thank you for reading this

KORAL STUDY OFFICE
Health Services Research Unit
University of Aberdeen
Foresterhill
Aberdeen, AB25 2ZD
Tel: 01224 554338
Fax: 01224 554580
Email: koral@abdn.ac.uk

Local details

Clinical lead:

Recruitment Officer: