



INFORMATION RE ADIPOA2 TRIAL

For departmental website <http://www.orthopaedics.cam.ac.uk/>

ADIPOA 2

A CLINICAL TRIAL FOR THE USE OF STEM CELLS FOR EARLY KNEE OSTEOARTHRITIS

Patients need to have osteoarthritis in one of their knees causing pain and swelling?

Traditionally the treatment for OA is to control the symptoms with medication until the disease progresses to a stage where joint replacement surgery may be required.

ADIPOA 2 is a pan European EU funded randomised controlled trial aiming to assess whether taking stem cells from abdominal fat cell, expanding the cell numbers and injecting them into the arthritic knee can have a positive effect on pain and function.

The study will be comparing Three randomly selected groups. The patients or investigator will not know which group the patients are in until after the study has finished. This is called a 'double blind' study and makes collected data more scientifically robust.

All patients will undergo a lipoaspiration (mini liposuction) from their abdominal wall under local anaesthetic to harvest the stem cells these will be sent to the lab for preparation. A knee injection will then be performed approximately two weeks later.

Group 1: Will receive an Injection of high dose stem cells,

Group 2: Will receive lower dose of stem cells.

Group 3: Will receive a placebo (no cells)

The study requires participation over **2 years**, with a total of **9 visits** to the hospital. These visits will vary in length and intensity, and the study team will discuss this with the patients before they agree to take part.

There is a list of criteria that each person must meet should they wish to participate in ADIPOA2. These will be discussed in greater detail during at the formal screening visit, but below is a list of some requirements which are essential for inclusion.

Inclusion criteria

- Aged 45-70
- BMI between 20-35
- Mild to moderate Osteoarthritis of one knee with swelling



- Pain in the knee for more than 6 months

Exclusion criteria – If patients meet any of the list below, they will be unable to take part in this trial

- Trauma or surgery of the knee within the last year
- Joint replacement of the hip or knee within the last year
- OA causing **significant** pain in any other joint
- Recent treatment with steroids (knee injection within past 6 months/oral therapy within past 3 months)
- History of heritable disorders (e.g hypermobility)
- Inflammatory or other rheumatic diseases
- Severe osteoporosis with previous vertebral or hip fractures
- Previous diagnosis/ treatment for cancer
- Pregnant women or women not using birth control
- Planned prolonged stay outside the region which prevents attendance to scheduled visits

If you have a patient who may be suitable please contact the study team, so that they can give the patient more information and discuss the study.

Many thanks

Mr Stephen McDonnell – Consultant Orthopaedic Surgeon / Study Coordinator

Professor Andrew McCaskie – Principle Investigator / Professor of Orthopaedics

Please contact: jennifer.ocallaghan@addenbrookes.nhs.uk for further trial information.