

# Intra-articular injection of fat micro graft: simple treatment for knee osteoarthritis with local injection of patient own fat

<b>Submission date</b> 26/04/2016	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 11/05/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 14/02/2018	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

In the normal joint, healthy cartilage allows bones to glide easily over each other. It also helps absorb shock of movement by its cushion like effect. Osteoarthritis is the most common joint disease that mostly affects cartilage particularly of major joints (such as the knee) due to chronic stresses on the joints from, for example, certain jobs and playing sports, obesity, genetic defects in joint cartilage or due to injury. It is common in the elderly due to wear and tear on the joint and rubbing of joint surfaces; this leads to destruction of cartilage and eventually narrowing of joint space, swelling, loss of joint movement, stiffness and significant pain. Pain is the most common symptom of osteoarthritis. It usually occurs when the joint is moved and improves at rest. It gradually becomes more severe due to the progression of disease and development of inflammation (swelling). The pain and stiffness affects the function of the joints and impacts upon a person's everyday life. Treatment focuses on pain relief and improving the physical function of the joint. In the most severe cases surgical replacement of the osteoarthritic joint can be performed, but this is major surgery and carries surgical risks and complications. The aim of this study is to look at whether an injection of fat from another area of the body into a knee with severe osteoarthritis improves their condition.

### Who can participate?

Adults with moderate to severe knee osteoarthritis

### What does the study involve?

Patients are first told what the treatment involves and are asked to give consent. The treatment involves using the self-lubricating effect of their own fat (autologous fat) inside the joint to improve joint function and reduce the pain and stiffness they experience. The surgical site for fat donation is selected according to patients' wishes and fat availability. The surgery is performed as day care surgery under local anaesthesia and sedation. During the surgery, the fat is obtained and prepared, then injected inside the joint cavity of the osteoarthritic knee. Patients are discharged soon afterwards with antibiotics and pain killers. All patients are then followed up to see if joint function has improved and whether there is a reduction in pain and stiffness of the joint.

What are the possible benefits and risks of participating?

Possible benefits include improvement in a patients quality of life and a reduction in the chance of severe joint damage and a reduced likelihood of needing joint replacement in the future.

Where is the study run from?

King Abdulaziz University Hospital (Saudi Arabia)

When is the study starting and how long is it expected to run for?

August 2010 to December 2016

Who is funding the study?

King Abdulaziz University Hospital

Who is the main contact?

Professor Sabah Moshref

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## Contact information

**Type(s)**

Scientific

**Contact name**

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## Additional identifiers

**Protocol serial number**

No. 822-12

## Study information

**Scientific Title**

Intra-articular Injection of autologous fat graft for the treatment of knee osteoarthritis

**Study objectives**

Does a simple injection of autologous fat graft improve chronic osteoarthritis

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Local Research and Ethics Committee, 15/05/2012, ref 822-12

**Study design**

Interventional study

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Osteoarthritis

**Interventions**

Patients are told what the treatment involves and are asked to give consent. The treatment involves using the self-lubricating effect of their own fat (autologous fat) inside the joint to improve joint function and reduce pain and stiffness. The surgical site for liposuction is then selected according to patients' wishes and fat availability. The surgery is performed as day care surgery under local anaesthesia and sedation under complete aseptic technique. During the surgery, the fat is obtained and prepared, then injected inside the joint cavity of the osteoarthritic knee via small microcannula. The patient is discharged with antibiotics and pain killers.

Post procedure all patients are followed up in the outpatient clinic on regular basis twice in the first month and then every three months to check for any side effects, complications, assessment of pain, stiffness and knee functions.

**Intervention Type**

Biological/Vaccine

**Primary outcome(s)**

Improvement in the pain and stiffness of the joint physical function by the combined lubricating and regenerative effect of fluid preparation. This is measured by pain experienced at rest and during activity using the visual analogue score (VAS) at preoperative visit and postoperative visit.

**Key secondary outcome(s)**

1. Joint physical function, measured using the Western Ontario and McMaster Universities Osteoarthritis Index at 3 months after surgery
2. Extent of repair of the osteoarthritic joint as indicated by arthroscopy of the fat injected joint (a minimally invasive surgical procedure to examine the damage of the joint) at 3 months after surgery

**Completion date**

29/12/2016

# Eligibility

## Key inclusion criteria

Adults with severe to moderate knee osteoarthritis changes, confirmed by bilateral anterior - posterior standing and lateral supine radiographs involving one or both knees

## Participant type(s)

Patient

## Healthy volunteers allowed

No

## Age group

Adult

## Sex

All

## Key exclusion criteria

1. Recent knee surgery
2. Chronic opioid intake
3. Bleeding disorders
4. Malignant disease
5. A congenital or traumatic deformity of the knee joint
6. Refusal of the patient to be included

## Date of first enrolment

20/12/2011

## Date of final enrolment

20/10/2015

# Locations

## Countries of recruitment

Saudi Arabia

## Study participating centre

King Abdulaziz University Hospital

P.O Box 80215

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# Sponsor information

**Organisation**

King Abdulaziz University Hospital

**ROR**

<https://ror.org/02ma4wv74>

**Funder(s)****Funder type**

Hospital/treatment centre

**Funder Name**

King Abdulaziz University Hospital

**Results and Publications****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Available on request

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Basic results</a>		11/01/2018	14/02/2018	No	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes