

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

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

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Non randomised study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

No participant information sheet available'

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 measure

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.

Secondary outcome measures

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

Overall study start date

29/08/2010

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

Age group

Adult

Sex

Both

Target number of participants

80

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

Sponsor details

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Sponsor type

University/education

ROR

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

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

King Abdulaziz University Hospital

Results and Publications

Publication and dissemination plan

We are planning to publish "Intra-articular Injection of Autologous Fat Graft for the Treatment of Knee Osteoarthritis" in a BMC journal.

Intention to publish date

31/12/2016

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?
Basic results		11/01/2018	14/02/2018	No	No