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Meniscal Transplantation and its Effect on Osteoarthritis Risk: a clinical trial of meniscal transplantation compared to personalised knee therapy

Submission date
27/11/2013

Recruitment status
No longer recruiting

Registration date
20/12/2013

Overall study status
Completed

Last Edited
07/03/2018

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
A meniscus is a shock absorber in the knee and protects it from impact. Tears of the meniscus are the most common knee injury. In most cases the torn portion of the meniscus has to be removed. It is well known that this increases the risk of arthritis in the knee and therefore the prospect of a knee replacement at a young age. Meniscal transplantation is currently provided by the NHS, but there is very little evidence to find out if a meniscal transplant protects the knee from arthritis. New advances in magnetic resonance imaging (MRI) have now enabled us to detect the early changes of arthritis in the knee, giving a new opportunity to find out whether meniscal transplantation may prevent arthritis.

Who can participate?
Adult men and women who have had previous removal of meniscus and who are currently having pain in the knee

What the study involve?
Patients willing to take part in the study will be allocated at random to either a meniscal transplant or personalised knee therapy (patients unwilling to be randomly allocated but willing to be included in the study will choose their treatment). They will be seen at the beginning of the study and 4, 8 and 12 months for follow up, where questionnaires and an MRI scan will be performed. Meniscal transplantation is through keyhole surgery. The new meniscus is from a donor and is inserted into the knee through a small cut at the front of the knee. It is held in position by strong stitches that are placed using the keyhole technique. The small wounds are then be stitched and a bandage is placed on the knee. After surgery, patients are given crutches to walk and a course of physiotherapy. Patients are able to put full weight on their leg at eight weeks after surgery. Personalised knee therapy is an exercise-based therapy course that has been specifically designed to treat patients with a symptomatic meniscal deficient knee. Each therapy course is unique, depending on the individual patients needs and will be designed by a senior physiotherapist. The course focuses on the symptoms of pain and swelling of the knee

and attempts to improve strength and range of movement. The course focuses on the knee joint but also addresses the hip, ankle and walking pattern as these can affect the knee. The course is delivered over at least a three-month period, which can be extended depending on the patients needs.

What are the possible benefits and risks of participating?
There are no specific benefits of taking part in this research. However, this study may help future patients decide about the best treatment for them. There are risks with meniscal transplant surgery, including surgical risks of tearing the new meniscus, persistent knee pain, infection and blood clots, but these are the same risks as for patients that do not take part in the study. The risks associated with personalised knee therapy are also the same for patients that do not take part in the study. There are no other special risks over and above what your doctor would normally inform you about.

Where is the study run from?
It is taking place at University Hospitals Coventry and Warwickshire (UHCW) NHS Trust (UK)

When is the study starting and how long is it expected to run for?
December 2013 to December 2015

Who is funding the study?
Arthritis Research UK

Who is the main contact?
Mr Nicholas Smith
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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
N/A

Study information

Scientific Title
A comprehensive cohort study of meniscal allograft transplantation versus personalised knee therapy for patients with a symptomatic meniscus deficient knee

Acronym
MeTEOR

Study objectives
The null hypothesis is that there is no difference in the mean change in cartilage volume in the weight-bearing area of the affected knee compartment one year post-intervention between patients with symptomatic meniscus-deficient knee treated with meniscal transplantation versus a personalised knee therapy programme.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee West Midland Solihull, 03/10/2013; ref:13/WM/0315

Study design
Comprehensive cohort study incorporating a randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Osteoarthritis / trauma / knee surgery

Interventions
Intervention: meniscal allograft transplantation using fresh frozen grafts. If the participant has a limb malalignment they will also be offered an osteotomy.

Comparator: personalised knee therapy course, which is a holistic exercise-based physiotherapy course, delivered over a minimum of three months.

Participants willing to be included in the randomised controlled trial will be randomised to either meniscal transplantation or personalised knee therapy. They will be followed up 4 monthly for a total of 1 year.

Participants that are unwilling to be randomised but willing to be included in the trial will choose their treatment (either meniscal transplantation or personalised knee therapy).

They will also be followed up 4 monthly for a total of 1 year. The randomised participants will have MRI scans 4 monthly and the non-randomised participants will have an MRI scan at baseline and at 1 year.

Intervention Type
Procedure/Surgery

Primary outcome measure
The mean change in cartilage volume in the central weight-bearing portion of the affected compartment of the knee between baseline and one year.

Secondary outcome measures
1. Knee injury and Osteoarthritis Outcome Score (KOOS)
2. Lysholm knee scores
3. International Knee Documentation Committee (IKDC) subjective knee scores
4. EuroQol EQ-5D
5. Complications
6. Health economic outcomes
7. Radiographic evaluation. The mean change in cartilage thickness in the central weight--bearing portion of the affected compartment will be measured. As well as this, T2 cartilage maps will be produced which give an assessment of cartilage quality.

All secondary outcome measures will be recorded at baseline, 4, 8 and 12 months, except health economics data, which will be recorded at 4, 8 and 12 months.

Overall study start date
28/11/2013

Completion date
01/12/2015

Eligibility

Key inclusion criteria
Patients (both male and female) will be eligible for this study if:
1. They have had a previous total or subtotal menisectomy (defined as deficient meniscal rim providing no circumferential fibre support or an intact rim of less than 2 mm width over the majority of the meniscus) and have current pain, swelling or stiffness in the affected compartment of the knee
2. The treating surgeon believes the patient may benefit from meniscal allograft transplantation

(MAT)
3. They are between the ages of 16 and 50 years and able to give informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
18 patients in the randomised trial

Key exclusion criteria
Patients will be excluded from participation in this study if:
1. They have had previous repair surgery on the articular cartilage of the affected compartment of the knee
2. They have grade 4 cartilage damage in the affected compartment of the knee according to the Outerbridge classification
3. There are contra-indications to anaesthetic
4. There is evidence that the patient would be unable to adhere to trial procedures or complete questionnaires, such as cognitive impairment or intravenous drug abuse

Date of first enrolment
28/11/2013

Date of final enrolment
01/12/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Clinical Sciences Research Laboratories
Coventry
United Kingdom
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Sponsor information

Organisation
University of Warwick (UK)

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Sponsor type
University/education

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ROR
https://ror.org/01a77tt86

Funder(s)

Funder type
Charity

Funder Name
Arthritis Research UK

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/06/2015		Yes	No
Results article	results	01/01/2018		Yes	No
HRA research summary			28/06/2023	No	No