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ABICUS trial

Submission date	Recruitment status	[X] Prospectively registered
04/05/2013	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
06/06/2013	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
01/09/2020	Musculoskeletal Diseases	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Damage to joint surface in the knee is commonly caused by sports injuries and falls. It does not restore itself when injured and ultimately the patient may develop arthritis in the knee joint. Many techniques have been developed to repair the damaged surface and the most commonly performed technique (gold standard) is micro fracture. In this procedure, drill holes are made in the damaged cartilage via a keyhole surgery (arthroscopy) to promote bleeding and scar tissue in place of the damaged surface. This technique has variable results and does not lead to the formation of new joint surface. Much research has been done on the ability of stems cells (patients own biological cells) to change into new joint surface cells. This study aims to find out the effectiveness of a new surgical procedure (ABICUS - Autologous Bone marrow Implantation of Cells University of Southampton), involving the use of patients own stem cells to restore joint surface in the knee and compare the results of this surgery with an existing, well established technique.

Who can participate?
Patients aged 18 to 65 with a proven joint defect in the knee

What does the study involve?
Patients are randomly allocated to one of two groups. Group 1 receive the conventional treatment (microfracture) and group 2 receive ABICUS. In group 2 patients, following anaesthesia, a sample of cells from inside the bone (bone marrow sample) is taken from the hip using a fine needle. A keyhole surgery of the knee is then performed and a mixture of the cells from the sample is collected and fibrin glue (an adhesive) is placed over the damaged area and allowed to set. Outcome scores using questionnaires and MRI scans of the knee are compared in the two groups.

What are the possible benefits and risks of participating?
There will be no risks different to those involved in the conventional treatment.

Where is the study run from?
University Hospital Southampton NHS Foundation Trust (UK)

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

Who is funding the study?
Neurotechnics Ltd (UK)

Who is the main contact?
Mr Gorav Datta
gdatta@doctors.org.uk

Study website
https://abicus-trial.com/

Contact information

Type(s)
Scientific

Contact name
Mr Gorav Datta

Contact details
Southampton General Hospital
Tremona Road
Southampton
United Kingdom
SO16 6YD

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1.1

Study information

Scientific Title
Autologous Bone Marrow Implantation University of Southampton (ABICUS) versus Microfracture in the knee

Acronym
ABICUS

Study objectives
ABICUS has a better clinical outcome than microfracture in the knee.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Not available at the time of registration

Study design
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
Musculoskeletal surgery

Interventions
1. Group 1: microfracture
2. Group 2: ABICUS (Autologous Bone Marrow Implantation University of Southampton) procedure

Intervention Type
Procedure/Surgery

Primary outcome measure
Clinical function, measured by the mean Lysholm, Knee injury and Osteoarthritis Outcome Score (KOOS) and International Knee Documentation Committee (IKDC) scoring scales at 6 weeks, 3 months, 6 months, 1 and 2 years post-operatively

Secondary outcome measures
Cartilage growth, assessed by MRI [Magnetic resonance Observation of CArtilage Repair Tissue (MOCART) score] at 1 and 2 years post-operatively

Overall study start date
01/07/2013

Completion date
01/07/2015

Eligibility

Key inclusion criteria
1. Participant is willing and able to give informed consent for participation in the study
2. Male or female, aged 18 years to 65 years
3. Diagnosed with articular cartilage defect in the knee as assessed on MRI scan
4. No other significant medical comorbidities (medical diseases)
5. Able and willing to comply with all study requirements

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Generalised and/or inflammatory arthritis
2. Active joint inflammation
3. Obvious deformity in the knee
4. Age below 18 and over 65 years
5. Significant medical comorbidities

Date of first enrolment
01/07/2013

Date of final enrolment
01/07/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Southampton General Hospital
Southampton
United Kingdom
SO16 6YD

Sponsor information

Organisation
Neurotechnics Limited (UK)

Sponsor details
c/o Gary Swattridge
Cephalon House
Unit 8 Manor Park
Banbury
Banbury
United Kingdom
OX16 3TB

Sponsor type
Industry

ROR
https://ror.org/03hmb2468

Funder(s)

Funder type
Industry

Funder Name
Neurotechnics Limited (UK)

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