# **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