

# ABICUS trial

<b>Submission date</b> 04/05/2013	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 06/06/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 01/09/2020	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Mr Gorav Datta

**Contact details**  
Southampton General Hospital  
Tremona Road  
Southampton  
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## Additional identifiers

**Protocol serial number**  
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

**Study type(s)**

Treatment

**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(s)**

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

**Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

### **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**

United Kingdom

England

### **Study participating centre**

**Southampton General Hospital**

Southampton

United Kingdom

SO16 6YD

## **Sponsor information**

### **Organisation**

Neurotechnics Limited (UK)

### **ROR**

<https://ror.org/03hmb2468>

## **Funder(s)**

### **Funder type**

Industry

### **Funder Name**

Neurotechnics Limited (UK)

## Results and Publications

### 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?
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes