

# Using autologous mesenchymal stem cells (MSC) to treat human fractures

<b>Submission date</b> 24/09/2009	<b>Recruitment status</b> Stopped	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 13/01/2010	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 01/02/2016	<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

[http://www.ctu.mrc.ac.uk/research\\_areas/study\\_details.aspx?s=87](http://www.ctu.mrc.ac.uk/research_areas/study_details.aspx?s=87)

## Contact information

### Type(s)

Scientific

### Contact name

Prof David Marsh

### Contact details

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## Additional identifiers

### Protocol serial number

G0900880

## Study information

### Scientific Title

Autologous cell therapy of fracture nonunion - cell phenotype as a predictor of outcome: a single blind randomised controlled trial

## **Acronym**

PACINO

## **Study objectives**

The study questions are:

1. Do culture-expanded, autologous mesenchymal stem cells (MSC) stimulate healing of nonunions more effectively than unmodified bone marrow?
2. Does the magnitude of the regenerative response correlate with any identifiable phenotypic features of the implanted cells?

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Outer North London Research Ethics Committee (REC) pending submission as of 29/09/2009.  
Planning to submit in October 2009.

## **Study design**

Single-blind randomised controlled trial using minimisation

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Tibial nonunion fractures

## **Interventions**

The standard treatment involves microdrilling holes across the docking site into which the patients own bone marrow is injected. This will be the treatment in the control arm of the trial. The study intervention will be the injection of the patients own mesenchymal stem cells (MSCs) into the microdrilled holes. Patients will receive one dose of either bone marrow or MSCs depending on whether they are in the control or intervention arm of the trial respectively. Treatment is a single dose of 30 million MSCs at the docking site, the follow-up is for one year post-docking.

## **Intervention Type**

Procedure/Surgery

## **Primary outcome(s)**

Change in bone mineral content (BMC) in a defined region of interest (ROI) around the docking site between 0 - 12 weeks after implantation, derived from computed tomography (CT) scans.

## **Key secondary outcome(s))**

Imaging-based:

1. X-Rays: bridging of 3 out of 4 cortices
2. Finite Element Analysis (FEA)
3. Reliable Unwrapping Susceptibility Technique (RUST) scores

The first antero-posterior (AP) and lateral radiographs will be taken prior to the segmental excision and after enrolment and then at 2 weekly intervals for 12 weeks with 3 radiographs in addition to standard care and then in line with standard care until week 52.

Clinical outcomes:

4. Short-form Musculoskeletal Function Assessment (SMFA)
5. Pain (Visual Analogue Scale [VAS])
6. Quality of life (36-item Short Form Health Survey [SF36]) and the need for re-operation

Patients will be asked to complete SF36 and SMFA questionnaires at 2, 12 and 25 weeks and VAS pain scores will be given in line with standard care.

**Completion date**

31/12/2013

**Reason abandoned (if study stopped)**

Participant recruitment issue

## **Eligibility**

**Key inclusion criteria**

1. Skeletally mature patients undergoing segmental excision of the tibia for nonunion followed by distraction osteogenesis and bone transport
2. Male and female patients
3. Over 18 years old with no upper age limit

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Congenital disorders
2. Pregnant or lactating women
3. Metabolic bone disease or bone active drugs
4. Anticipated problems with maintaining follow-up

**Date of first enrolment**

01/01/2010

**Date of final enrolment**

31/12/2013

## Locations

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

Royal National Orthopaedic Hospital

London

United Kingdom

HA7 4LP

## Sponsor information

**Organisation**

Joint UCLH and UCL Biomedical Research Unit (UK)

**ROR**

<https://ror.org/03r9qc142>

## Funder(s)

**Funder type**

Research council

**Funder Name**

Medical Research Council (MRC) (UK) - Translational stem cell research programme: Response mode funding (ref: G0900880)

**Alternative Name(s)**

Medical Research Council (United Kingdom), UK Medical Research Council, MRC

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**  
United Kingdom

## 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="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes