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

Submission date	Recruitment status	[ ] Prospectively registered
24/09/2009	Stopped	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
13/01/2010	Stopped	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
01/02/2016	Musculoskeletal Diseases	[ ] Record updated in last year

Plain English summary of protocol
http://www.ctu.mrc.ac.uk/research_areas/study_details.aspx?s=87

Contact information

Type(s)
Scientific

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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. Treament 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, Medical Research Committee and Advisory 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