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

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

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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 below to request a patient information sheet

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 measure
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.

Secondary outcome measures
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.

Overall study start date
01/01/2010

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

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

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
England

United Kingdom

Study participating centre
Royal National Orthopaedic Hospital
London
United Kingdom
HA7 4LP

Sponsor information

Organisation
Joint UCLH and UCL Biomedical Research Unit (UK)

Sponsor details
c/o Dr Nick McNally
1st Floor, Maples House
Ground Floor, Rosenheim Wing

25 Grafton Way
London
England
United Kingdom
WC1E 6DB

Sponsor type
Hospital/treatment centre

Website
http://www.ucl.ac.uk/joint-rd-unit/

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

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