ISRCTN29808592 https://doi.org/10.1186/ISRCTN29808592

A novel minimally invasive surgical procedure for the treatment of femoral diaphyseal nonunions

Submission date
02/09/2017

Recruitment status
No longer recruiting

Registration date
12/09/2017

Overall study status
Completed

Last Edited
25/11/2020

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Diaphyseal femoral fractures (breaks in the large leg bone) occur in both the young and the elderly. Current methods include intramedullary nailing (having a metal rod forced into the bone), plate fixation, and external fixation (procedures that fix screws or plates to the bone). However, in patients treated with these methods, 0.9 - 4% of nonunion (when the bone fails to heal) rate is reported. The treatment of nonunions is a challenge to orthopedic surgeons. For patients with atrophic femoral diaphyseal nonunions (wasting away of the bone), autologous cancellous bone (bone grafts) is a fairly common practice, with the most common autologous graft donor site being the iliac crest. The incidence of morbidities (co-occuring diseases) related to bone grafts is as high as 22%. To minimize the drawbacks associated with traditional bone grafting, percutaneous approaches (made through the skin) have been developed for harvesting autologous bone marrow. However, not all patients who undergo this procedure experience satisfactory healing, and the incidence of nonunion after BM injection continues to be high, at 18 - 37%. Prior to this study, we carefully assessed the drawbacks associated with previously reported autologous BM transplantation procedures, and designed a modified surgical method. This study is to examine the outcomes of multidirectional percutaneous drilling combined with autologous concentrated BM transplantation for atrophic femoral diaphyseal nonunions characterized by intact hardware and mechanical stability at the nonunion site.

Who can participate?
Adults aged 18 or over who have an atrophic nonunion of femoral diaphysis.

What does the study involve?
All participants undergo combined multidirectional percutaneous drilling and autologous BM transplantation. Surgery is scheduled after completing the routine examination, which will take approximately two-three days. Around four to five days of observation period is arranged after operation.Following the surgery, participants return every month and the second-stage follow-up are carried out at each visit. Participants are followed up to see how well their bones healed and if there were any complications.

What are the possible benefits and risks of participating?
There are no direct benefits. Bone union is expected. The related technique is already mature. Local complication is rarely reported. Possible complications include mild pain, redness or swelling in the operation area.

Where is the study run from?
Chinese PLA General Hospital (CN)

When is study starting and how long is it expected to run for?
January 2008 to June 2018

Who is funding the study?
Chinese PLA General Hospital (CN)

Who is the main contact?
Professor Peifu Tang

Contact information

Type(s)
Scientific

Contact name
Prof Peifu Tang

Contact details
Department of Orthopaedics
Chinese PLA General Hospital
28 Fuxing Road
Haidian District
Beijing
China
100853

Type(s)
Public

Contact name
Dr Yutong Meng

Contact details
Department of Orthopaedics
Chinese PLA General Hospital
28 Fuxing Road
Haidian District
Beijing
China
100853

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Not Applicable

Study information

Scientific Title
Clinical outcome of a modified autologous BM transplantation vs. previously reported BM transplantation for the treatment of femoral diaphyseal nonunions

Study objectives
Combined multidirectional percutaneous drilling and autologous BM transplantation performs better than traditional autologous BM transplantation alone in femoral diaphyseal nonunions.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Ethical Review Committee of Chinese PLA General Hospital, 01/12/2008

Study design
A prospective single-center single-group interventional study

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
Femoral diaphyseal nonunions

Interventions
This study is a prospective single-group interventional study. All the participants in this study are allocated to the treatment group. All participants undergo the surgery of combined

multidirectional percutaneous drilling and autologous BM transplantation. Surgery is scheduled after completing the routine examination, which will take approximately two-three days. Around four to five days of observation period is arranged after operation. The first-stage treatment will last for 6-8 days.

Following the surgery, participants return every month and the second-stage follow-up will be carried out at each visit. The follow-up items are listed as follows:
1. Radiographic examinations
2. RUST score based on radiographic evaluation
3. Any postoperative complications

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Healing condition of cortices is measured using the Radiographic Union Scale for Tibial fractures (RUST) every month after operation
2. Bony union time is recorded when radiographic union is achieved, which was diagnosed by a RUST score ≥ 10

Secondary outcome measures
1. Postoperative complications is collected from medical records at discharge from hospital
2. Health Economic assessment is assessed using length of hospital stay and serious adverse events including death within 90 days of surgery

Overall study start date
01/07/2008

Completion date
30/06/2018

Eligibility

Key inclusion criteria
1. Presenting with atrophic nonunion of femoral diaphysis
2. Adults aged 18 or over

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

10

Total final enrolment
14

Key exclusion criteria
1. Participant with local angular deformity
2. Participant with extremity shortening
3. Participant with internal fixation failure
4. Participant with mental comorbidity

Date of first enrolment
01/01/2009

Date of final enrolment
30/09/2013

Locations

Countries of recruitment
China

Study participating centre
Chinese PLA General Hospital
China
100853

Sponsor information

Organisation
Chinese PLA General Hospital

Sponsor details
28 Fuxing Road
Haidian District
Beijing
China
100853

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04gw3ra78

Funder(s)

Funder type
Not defined

Funder Name
Chinese PLA General Hospital

Results and Publications

Publication and dissemination plan
Analysis of relevant data of this study is being carried out. The main results will be published in a high-impact peer-reviewed journal.

Intention to publish date
01/01/2018

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	19/08/2019	25/11/2020	Yes	No