The effect of concentrated bone marrow aspirate in operative treatment of fifth metatarsal stress fractures

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON19971

Source
NTR

Brief title
cBMA in MT-V stress fractures

Health condition

stress fracture, stressfractuur, fifth metatarsal, vijfde os metatarsale, bone marrow, beenmerg, stem cells, stamcellen

Sponsors and support

Primary sponsor: Academic Medical Center (AMC) Amsterdam, Orthopaedic Research Center Amsterdam (ORCA) Department of Orthopaedics, The Netherlands
Source(s) of monetary or material Support: Orthopaedic Research Center Amsterdam (ORCA), Biomet, Marti-Keuning Eckhart Foundation

Intervention

Outcome measures

Primary outcome

Radiological time to fracture union in weeks

Secondary outcome

Clinical time to union in weeks, time to return to sport and work or activities (in weeks), union rate (in %), patient function and satisfaction (SF-12, AOFAS, FAAM), complication rate, safety and cost-effectiveness.
Furthermore from all patients, a bone biopsy will be taken and analyzed to achieve information of the stage of fracture healing at the time of operation. Also all obtained cBMA will be analyzed in the laboratory and quality and osteogenic activity of the aspirate is measured by means of CD34, CD45, CD90, CD105, CD146, CD271 count, CFUF assay and in a later stadium mRNA analysis. Patients characteristics (including foot type, shoe brand, age, weight, etc) are also recorded

Study description

Background summary

Rationale: Fifth metatarsal (MT-V) stress fractures are ill-famed for their long time to union. Even the current gold standard, being operative treatment, does not present optimal results with a mean time to fracture union of grossly 12-18 weeks. The aim of this randomized trial is to study if it is possible to shorten this time to fracture union after operative treatment of MTV
stress fractures with use of concentrated bone marrow aspirate (cBMA).
Objective: To study the effect of using cBMA in the operative treatment of MT-V stress fractures on the time to fracture healing.
Study design: A prospective, randomized controlled trial.
Study population: Skeletally mature patients with clinically an MT-V stress fracture
Intervention: Every fracture will be treated operatively by intramedullairy screw fixation with an internal bone graft from the decortication along the fracture lines. In the intervention group, a bone marrow aspirate is harvested from the iliac crest during the operation. This aspirate is concentrated and as cBMA put into and around the fracture using the internal decortication as a natural scaffold. The control group will undergo a sham procedure (only a skin wound on the iliac crest) without adding cBMA. Rehabilitation and follow up is the same for both groups.
Main primary endpoints: radiological time to fracture union (in weeks). Main secondary endpoints: clinical time to union (in weeks), time to return to sport and/or work (weeks), union rate (%), patient function and satisfaction (SF-12, AOFAS, FAAM), complication rate and cost-effectiveness. In laboratory the stage of the stress fractures will be analyzed as well as the composition and osteoprogenitor activity of the cBMA.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Surgery can lead to the common complications of surgery like local hematoma, neurological failure and infection. Possible known risks of collecting cBMA from the iliac crest are hematoma, (temporary) hyper/hypoesthesia, infection, and pain. The only

known risk of adding the cBMA at the fracture site is local pain. Participation requires no extra OR time and the intervention could give shorter time to union and time to return to work, sports and activities, also less nonunions and thus potentially a significant decrease in costs.

Study objective

Operative treatment with additional concentrated bone marrow cells results in better fifth metatarsal stress fracture healing than operative treatment alone. We furthermore hypothesize that composition of bone marrow cells also contributes to healing time.

Study design

Baseline visit is pre-operative, the next visit is intra-operative and immediate post-operative. Follow-up will be every 2 weeks, up until the 14th week and, after that, only in the patients in which union has not yet occurred as deemed necessary by the treating physician. Next follow-up visit is at 6 months and the last one is one year after surgery.

Intervention

All patients will be treated surgically with open reduction and internal fixation with an intramedullairy screw, combined with a decortication and internal bone graft of the fracture site. The rehabilitation protocol for the first 8 weeks after operation is set standard for both intervention and control group; first two weeks non weight bearing-cast, than 2 weeks partial weight bearing cast, thereafter 4 weeks in a weight bearing cast or walker.
On every patient in the intervention group, a bone marrow draw is performed by the orthopaedic surgeon while under anaesthesia in the OR, through needle aspiration from patient’s own iliac crest. The cells are concentrated by utilizing MarrowStim Concentration System (Biomet) which centrifuges the cells into an efficient concentration of autologous bone marrow aspirate (cBMA). This cBMA is added to the fracture together with the internal bone graft. In the control group only a skin inciscion at the iliac crest is performed (sham procedure to ensure blinding)

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Eligibility criteria

Inclusion criteria

- MT-V stress fracture diagnosed on physical examination and X-ray
- Skeletally mature patients

Exclusion criteria

- Expected non-compliance; patients who are unable to fill out questionnaires and cannot have them filled out
- Patients participating in another clinical trial
- Patients suffering from auto-immune disease
- Patients receiving biologicals, prednisolon or some kind of chemotherapy < 1 year
- Concomitant painful or disabling disease of the lower limb
- No informed consent
- Pregnant and nursing women
- Active malignancy

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2014
Enrollment:	50
Type:	Anticipated

Ethics review

Positive opinion

Date:	04-02-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 38972
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4232
NTR-old	NTR4377
CCMO	NL44856.018.13
OMON	NL-OMON38972

Study results

Summary results

N/A