Effect of Computer-Controlled Cooling on Surgical Aspects after a Displaced Intra-Articular Calcaneal Fracture (Cool-DIACF); A Multicenter Randomized Controlled Trial

No registrations found.

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

Summary

ID

NL-OMON20937

Source
Nationaal Trial Register

Brief title
Cool-DIACF

Health condition

Displaced intra-articular calcaneal fracture (DIACF)

Sponsors and support

Primary sponsor: Erasmus MC, University Medical Center Rotterdam, Trauma Research Unit, Department of Surgery
Erasmus Medical Center, Medical Research Ethics Committee (MREC)
Source(s) of monetary or material Support: cCare Orthopedics B.V.

Intervention

Outcome measures

Primary outcome

Time to surgery

Secondary outcome

Preoperative and postoperative pain; Preoperative and postoperative swelling; Preoperative and postoperative foot/ankle circumference; Postoperative hospital length of stay; Satisfaction with the approach to reduce swelling; Adverse events within three months after surgery.

Study description

Background summary

BACKGROUND
Displaced intra-articular calcaneal fractures (DIACF) are challenging to treat and are associated with a long rehabilitation period. As the incidence shows a peak in persons in their wage-earning population, the burden to society is high. Surgery should be done as soon as possible. Timing of surgery is mostly determined by the amount of swelling that occurs after trauma. Swelling occurring after surgery may increase the risk of disturbed wound healing and prolong hospital length of stay. Cooling devices have been developed in order to reduce preoperative and postoperative swelling. Furthermore cooling may reduce the need for analgesics. Cooling is expected to result in earlier surgery, shorter hospital length of stay and earlier mobilization, which in turn reduces the risk of adverse events.

AIM
The primary aim of this study is to examine the effect of preoperative cooling versus pressure bandage on the time to surgery in adult patients who sustained a displaced intra-articular calcaneal fracture (DIACF) that will be treated operatively using an extended lateral approach.
The secondary aims are to examine in these patients:

1) the effect of preoperative and postoperative cooling versus pressure bandage on the level of preoperative and postoperative pain.

2) the effect of preoperative and postoperative cooling versus pressure bandage on preoperative and postoperative swelling.

3) the effect of preoperative and postoperative cooling versus pressure bandage on

foot/ankle circumference.

4) the effect of postoperative cooling versus pressure bandage on postoperative hospital length of stay.

5) patient satisfaction with the approach to reduce swelling (cooling versus pressure bandage).

6) the effect of preoperative and postoperative cooling versus pressure bandage on the rate of complications.

STUDY DESIGN
Multicenter Randomized Controlled Trial (RCT)

POPULATION
Adult persons aged 18 years or older presenting to the Emergency Department with a unilateral, displaced, intra-articular calcaneal fracture (Sanders type III/V or OTA type 82C24), with an indication for treatment by open reposition and internal fixation (ORIF) using an extended lateral approach.

INTERVENTION
Patients will be equally randomized to two groups:

1) Computer-controlled cooling brace

2) Pressure bandage

ENDPOINTS
Primary outcome measure: Time to surgery
Secondary outcome measures: Preoperative and postoperative pain; Preoperative and postoperative swelling; Preoperative and postoperative foot/ankle circumference; Postoperative hospital length of stay; Satisfaction with the approach to reduce swelling; Adverse events within three months after surgery

Data will be collected daily from hospital presentation until day 7 after surgery and at 2 weeks, 6 weeks, and 3 months after surgery.

RECRUITING COUNTRIES

The Netherlands

Study objective

We expect that preoperative and postoperative cooling will reduce swelling faster, reducing the time to surgery and time to discharge, respectively.

Study design

Daily from hospital presentation until day 7 after surgery and at 2 weeks, 6 weeks, and 3 months after surgery.

Intervention

Patients in the group will be treated with a computer-controlled cooling brace. The control group will receive a pressure bandage without cooling.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients with a displaced (>2 mm step-off in posterior facet), intra-articular calcaneal fracture (Sanders type II-IV or OTA type 82C2-4)

2. Indication for ORIF using an extended lateral approach

3. Adult men or women aged 18 years or older

4. Hospital presentation within two days after trauma*

5. Provision of informed consent by patient

Exclusion criteria

1. Patients with an existing condition that result in asymmetrical morphometric characteristics of the distal part of either one of the lower legs

2. Additional traumatic injuries that might influence extremity volume (e.g., lower extremity fracture, pelvic fracture)

3. Patients with bilateral calcaneal fractures

4. Patients with a pathological, recurrent, or open calcaneal fracture

5. Patients with decreased sensory function in any leg that might affect pain sensation.

6. Patients not fit for surgery

7. Patients unwilling or unable to comply with the intervention or follow-up visit schedule

8. Insufficient comprehension of Dutch or English language to understand rehabilitation programs and other treatment information in the judgment of the attending physician

9. Participation in another surgical intervention or drug study that might influence any of the outcome parameters

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	01-01-2016
Enrollment:	36
Type:	Anticipated

Ethics review

Positive opinion

Date:	05-01-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5468
NTR-old	NTR5612
Other	NL54213.078.15 : MEC-2015-592 (METC Erasmus MC)

Study results

Summary results

None yet; study is ongoing