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

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Primary Objective:To examine the effect of pre-operative 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...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Fractures
Study type	Interventional

Summary

ID

NL-OMON44652

Source
ToetsingOnline

Brief title
Cool-DIACF

Condition

- Fractures

Synonym
Calcaneal fracture; hindfoot fracture

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Calcaneus, Cooling, Cryotherapy, Fracture

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

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.

Study objective

Primary Objective:
To examine the effect of pre-operative 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 or sinus tarsi approach.

Secondary Objective(s):
1) To examine the effect of pre- and post-operative cooling versus pressure bandage on the level of pre- and postoperative pain in adult patients who sustained a DIACF.
2) To examine the effect of pre- and postoperative cooling versus pressure bandage on preoperative and postoperative swelling in adult patients who sustained a calcaneal fracture.
3) To examine the effect of pre- and postoperative cooling versus pressure bandage on foot/ankle circumference in adult patients who sustained a DIACF.
4) To examine the effect of postoperative cooling versus pressure bandage on postoperative hospital length of stay in adult patients who sustained a calcaneal fracture.
5) To examine patient satisfaction with the approach to reduce swelling (cooling versus pressure bandage) in adult patients who sustained a calcaneal fracture.
6) To examine the effect of pre- and postoperative cooling versus pressure bandage on the rate of complications in adult patients who sustained a calcaneal fracture.

Study design

Multicenter Randomized Controlled Trial (RCT)

Intervention

Patients will be equally randomized to two groups:
1) Computer-controlled cooling brace
2) Pressure bandage

Study burden and risks

The intervention and control treatment are both standard of care, which generally includes hospital admission. The follow-up program (outpatient department visits, physical examination, and diagnostics) is standard for the targeted population.
From enrolment until surgery, patients will be subjected daily to: 1) 5x

completion of pain question; 2) digital photo of affected foot
From enrolment until surgery, patients will also be subjected day 1 and 2 and then every second day to: 1) duplicate measurement of foot/ankle circumference on both sides; 2) duplicate measure of foot/ankle volume on both sides;
At day 2 and 7 postoperative, patients will be subjected to: 1) 1x completion of pain question; 2) duplicate measurement of foot/ankle circumference; 3) duplicate measure of foot/ankle volume; 4) digital photo of affected foot.
On the day of surgery and day 7 after surgery, patients will complete a VAS for patient satisfaction with the approach to reduce swelling.
Follow-up data will be collected daily from hospital admission until discharge, and at two weeks, six weeks, and three months after primary surgery. At each visit, patients will be subjected to: 1) 1x completion of pain question; 2) duplicate measurement of foot/ankle circumference; 3) duplicate measure of foot/ankle volume; 4) digital photo of affected foot.
Therefore there is no additional risk for patients participating in this study.
The risk for study participants is the same as for patients who do not participate

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

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 (8); confirmed on X-ray (lateral and AP with Brodèn view) or CT)
2. Indication for ORIF using an extended lateral or sinus tarsi 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 a 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 unfit 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:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-10-2016
Enrollment:	36
Type:	Actual

Ethics review

Approved WMO Date:	29-10-2015
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	28-07-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	02-12-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	14-03-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
CCMO	NL54213.078.15