

# 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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<b>Ethische beoordeling</b>	Positief advies
<b>Status</b>	Werving tijdelijk gestopt
<b>Type aandoening</b>	-
<b>Onderzoekstype</b>	Interventie onderzoek

## Samenvatting

### ID

NL-OMON20937

### Bron

Nationaal Trial Register

### Verkorte titel

Cool-DIACF

### Aandoening

Displaced intra-articular calcaneal fracture (DIACF)

### Ondersteuning

**Primaire sponsor:** Erasmus MC, University Medical Center Rotterdam, Trauma Research Unit, Department of Surgery

Erasmus Medical Center, Medical Research Ethics Committee (MREC)

**Overige ondersteuning:** cCare Orthopedics B.V.

# Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

Time to surgery

## Toelichting onderzoek

### Achtergrond van het onderzoek

#### 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

## Doel van het onderzoek

We expect that preoperative and postoperative cooling will reduce swelling faster, reducing

the time to surgery and time to discharge, respectively.

### **Onderzoeksopzet**

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

### **Onderzoeksproduct en/of interventie**

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

## **Contactpersonen**

### **Publiek**

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### **Wetenschappelijk**

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## **Deelname eisen**

### **Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)**

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

## **Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)**

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

## **Onderzoeksopzet**

### **Opzet**

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

## Deelname

Nederland  
Status: Werving tijdelijk gestopt  
(Verwachte) startdatum: 01-01-2016  
Aantal proefpersonen: 36  
Type: Verwachte startdatum

## Ethische beoordeling

Positief advies  
Datum: 05-01-2016  
Soort: Eerste indiening

## Registraties

### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

### Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

### In overige registers

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

## Resultaten

### Samenvatting resultaten

None yet; study is ongoing