

# Prospective, randomised, open-label study to skin-friendliness and usability of Delta-dry vs. regular padding at lower-arm cast, scaphoid cast and lower-leg cast.

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How friendly is Delta-dry to the skin versus regular padding? Will Delta-dry be more functional than regular padding in patient experience? (Functional as in daily activity's concentrated to getting wet of the cast) How is the processability of...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Will not start
<b>Health condition type</b>	Fractures
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON33931

### Source

ToetsingOnline

### Brief title

Delta-Dry vs. regular padding

### Condition

- Fractures

### Synonym

cast, fractures

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Utrecht

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** cast, fracture, padding, skincondition

## Outcome measures

### Primary outcome

The skin-friendliness will be scored by the skin-therapist on general skin-condition, maceration, redness, wounds, hives and squama. The scoring will be done based on photographs made before casting-treatment and 2 weeks after.

### Secondary outcome

The functionality will be scored by the patients on: general impression, comfort, time of getting dry, swimming, washing and showering, itching, pain, oppressive nature and smell.

The processability by the casting technician will be scored on: general impression, steerability, combatibility, time needed, finishing and removeability.

## Study description

### Background summary

Before establishing plaster, we always start with a layer of padding between the skin and the plaster. This is to protect the skin against pressure points for example and to easily remove the cast. The regular padding, a cotton stocking, cotton-wool and pre-tape, underneath the plaster is not allowed to get wet. This could give damage of the skin.

Since a while, a new padding exists, Delta-dry. This padding is allowed to get wet, so the patients could take a shower without covering the cast. Delta-dry is a polyester, water won't be absorbed by this, it's waterresistant. This padding wouldn't damage the skin and it should have the same protection en comfort as the regular padding.

### **Study objective**

How friendly is Delta-dry to the skin versus regular padding?

Will Delta-dry be more functional than regular padding in patient experience?

(Functional as in daily activity's concentrated to getting wet of the cast)

How is the processability of Delta-dry versus regular padding by the experience of the casting technician?

### **Study design**

The study design involves a prospective, randomised, open-label study (partial blinding) to skin-friendliness and usability of Delta-dry versus regular padding

### **Study burden and risks**

Because of the randomisation, the patient has no control on the kind of padding that will be used.

There are no risks, other then the risks of regular casting treatment. Possible benefits or disadvantages of the paddings are unknown, these will be examined in this study.

## **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

All patients who need a circulaire casting treatment of the lower-arm, scaphoid or lower-leg, prescribed by their physicians, can be included.

### Exclusion criteria

Patients with wounds, skin-diseases like psoriasis or eczema, or fractures after reducing will be excluded.

## Study design

### Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

### Recruitment

NL

Recruitment status:	Will not start
Start date (anticipated):	15-01-2009
Enrollment:	125
Type:	Anticipated

## Ethics review

Approved WMO	
Date:	23-06-2009
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

## 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	NL26220.041.08