Vacoped Protocol Studie

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26630

Source
Nationaal Trial Register

Brief title
-

Health condition

Injuries to fibula, distal tibia, achilles tendon and foot; in particular ankle fractures
Letsels aan het onderbeen/de voet

Sponsors and support

Primary sponsor: None
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

Functional results

Complication rates

Secondary outcome

Functional results per Vacoped protocol

Complication rates per Vacoped protocol

Patient perception of the Vacoped

Study description

Study objective

1. A safe and effective treatment protocol for the Vacoped is: Application of the Vacoped in the operating theatre/emergency department, with partial load-bearing up to 20 kg allowed from day 2. Full load bearing is allowed from day 10-14, with a total treatment duration of 6 weeks.

2. The Vacoped is comfortabel, easy to use and causes little pain.

3. Usage of the Vacoped leads to quick restoration of functionality without a high rate of complications.

4. The Vacoped achieves functional results which are at least as good as normal plaster cast, and is at least as safe.

Study design

2 months post-treatment

Intervention

Vacoped walker

Contacts

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Eligibility criteria

Inclusion criteria

Trauma to the foot or inferior lower limb, age 16 years or older, treated in the Atrium Medisch Centrum in Heerlen, where treatment has been with either the Vacoped or plaster cast.

Exclusion criteria

Open fractures, medical conditions limiting use of arms/hands

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	16-06-2014
Enrollment:	128

Type:	Anticipated

Ethics review

Positive opinion

Date:	11-06-2014
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	NL4552
NTR-old	NTR4696
Other	: -

Study results