Pulsed electromagnetic fields in the treatment of fresh scaphoid fractures. Clinical and radiological outcome. A multi centre, prospective, double-blind, placebo controlled, randomized trial.

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Fractures
Study type	Interventional

Summary

ID

NL-OMON33275

Source
ToetsingOnline

Brief title
Pulsed electromagnetic fields in the treatment of fresh scaphoid fractures.

Condition

- Fractures

Synonym
healing disorder, scaphoid non-union

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: electromagnetic fields, multi centre trial, randomized controlled trial, scaphoid bone

Outcome measures

Primary outcome

Primary endpoint is number of scaphoid fracture unions (healed fractures) at

six weeks.

Secondary outcome

Secondary endpoints are time interval to clinical and radiological

consolidation, number of non-unions, functional status at 52 weeks and

non-adherence to the treatment protocol.

Study description

Background summary

The scaphoid fracture is a troublesome fracture and failure of treatment can result in avascular necrosis (up to 40%), non-union (5-21%) and early osteo-arthritis (up to 32%) which may seriously impair wrist function. In addition impaired consolidation of scaphoid fractures results in longer immobilization and more days lost at work with significant psychosocial and financial consequences.
Studies showed that even uncomplicated healing leads to a mean employment interruption of 155 days. Furthermore patient population mainly consist of young, active men and women aged 15 to 40 and therefore economic consequences of temporary or even permanent disability are substantial.
Current treatment strategies are unable to deal with this problem since exact outcome after scaphoid union, non-union and other complications such as avascular necrosis remains unclear. Even after operative treatment results are variable. Furthermore operative treatment for complicated healing of scaphoid

fractures (eg delayed or non-union) is often initiated in a late fase, most often months after the fracture occured.
Initially PEMF (pulsed electromagnetic fields) was used in the treatment of tibial pseudoarthrosis and non-union. More recently there is evidence that physical forces can also be used in the treatment of fresh fractures, showing accelerated healing by 30 % and 71 % reduction in non-union within 12 weeks after initiation of therapy.
We therefore want to investigate whether the use of PEMF in fresh scaphoid fractures accelerates consolidation of this fracture and whether the use of PEMF reduces the incidence of disabling wrist conditions like scaphoid non-union or osteonecrosis.

Study objective

The objective of this study is:

1.To determine whether the use of bone-growth stimulation by means of pulsed electromagnetic fields (PEMF) in fresh scaphoid fractures will accelerate healing both clinically and radiologically.

2.To determine whether the use of PEMF in fresh scaphoid fractures will decrease the incidence of non-unions and avascular necrosis of the scaphoid and therefore the number of secondary surgical interventions.

3.To investigate the effect of PEMF in scaphoid fractures on functional outcome.

4.To investigate the potential cost-effectiveness of PEMF from a societal perspective when compared with care as usual.

Study design

This is a multi centre, prospective, double-blind, placebo controlled, randomized trial.
Study parameters are clinical consolidation, radiological consolidation by means of CT scanning, functional status of the wrist, including the patient rated wrist evaluation (PRWE) and quality of life, measured by SF-36 health survey questionnaire.

Intervention

All patients having a proven scaphoid fracture are treated with cast immobilisation and a small PEMF device placed on the cast. Half of the PEMF devices will be disabled at random in the factory. The patients as well as the investigators will be unaware of the device's functionality.
The small PEMF device will be placed on the cast within five days after diagnosing the fracture and will be applied for 24 hours a day continuously.

Dependant on fracture consolidation, the device will be removed after six to twelve weeks.
Follow up will take place acoording to a fixed protocol.

Study burden and risks

All patients will be subjected to two or three extra visits to the outpatient clinic. These visits will take 10 to 15 minutes extra. Furthermore they will be asked to fill out two questionnaires, the PRWE and the SF-36 questionnaire. Two or three extra CT-scans of the wrist will be made. Benefit for the patients is that all patients will have substantial better control of the healing of their fracture.
No negative effects of treatment with the PEMF device have been reported. Concerning safety of the diagnostic interventions, the amount of additional generated radiation is very low. The average amount of generated radiation when performing a CT scan of the wrist is 0.045 mSv. The average amount of radiation from artificial sources used in medicine each person is exposed to in the Netherlands is 0.7 mSv each year. The total amount of received radiation is 2 to 2.7 mSv annually in the Netherlands. When concerning these numbers, the added amount of radiation is negligible.

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 unilateral fresh scaphoid fractures, types A1, A2, B2 and B3 (all stable and unstable acute fractures except the dislocated and comminuted ones) according to the Herbert classification of scaphoid fractures.

Exclusion criteria

Exclusion criteria are pregnancy, presence of a life-supporting implanted electronical device, additional fractures of wrist, carpal or metacarpal bones and pre-existing impairment in wrist function.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2010
Enrollment:	110
Type:	Actual

Medical products/devices used

Generic name:	PEMF (pulsed electromagnetic fields) - bone growth stimulator
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	21-09-2009
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL27191.091.09