Pulsed Electromagnetic Fields in the treatment of fresh scaphoid fractures. Clinical and radiological outcome. A multicentre, prospective, double-blind, placebo-controlled, randomized trial. (CMO nr 2009/196) (ABR nr NL27191.091.09).

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27135

Source
Nationaal Trial Register

Brief title
Scaphoid trial

Health condition

scaphoid fracture, bone growth stimulation, electromagnetic fields, fracture healing, ununited fracture, double-blind method

Sponsors and support

Primary sponsor: ZonMW, academisch ziekenhuis Maastricht
Source(s) of monetary or material Support: zonMW, academisch ziekenhuis Maastricht

Intervention

Outcome measures

Primary outcome

Radiological proof of union of the scaphoid fracture at six weeks after initiation of the electromagnetic stimulation, determined by means of CT-scanning.

Secondary outcome

1. Radiological and clinical consolidation at 24 weeks (non-union ?);

2. Functional outcome and quality of life at 52 weeks.

Study description

Background summary

The scaphoid bone is the most commonly fractured of the carpal bones. The scaphoid has an essential role in functionality of the wrist, acting as a pivot and complications in healing can result in poor functional outcome. 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.

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 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. Nevertheless, until now no double blind randomized, placebo controlled trial has been conducted to investigate the effect of PEMF on the healing

of fresh fractures of the scaphoid bone and investigate the effects of this treatment on consolidation and prevention or reduction of complications of healing, such as non-union.

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 and the consequences of this treatment on time off work and resuming of former professional activities.

This is a multi centre, prospective, double-blind, placebo controlled, randomized trial. Study population consists of all patients with an unilateral fresh scaphoid fracture. Pregnant women and patients having a life-supporting implanted electronic device are excluded as well as patients with additional fractures of wrist, carpal or metacarpal bones and pre-existing impairment in wrist function.

A fracture of the scaphoid bone is diagnosed by a combination of physical and radiographic examination. (CT-scanning)

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. Follow up will take place according to a fixed protocol.

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.

Primary endpoint is number of scaphoid fracture unions at six weeks, 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.

The estimated incidence of scaphoid fractures is about 35 per year in a hospital with an adherence of 250.000 patients a year. Studies performed using physical forces on fresh fractures show acceleration of the healing process of about 30 %. Based on a power analysis a study group of 100 to 110 patients is needed for inclusion. (alpha 0.05, beta 0.20, 81 % vs 55 % consolidation after 6 weeks, including 15 % dropout).

If the results of this treatment are as we suspect, based on former studies using physical forces to accelerate bone healing, a financial benefit is also created because of faster and enhanced recovery of troublesome scaphoid fractures in a young and productive patient population. This financial benefit is greater than the coststs involved in this treatment, based on the number of patients (earlier) resuming their former professional activities.

Study objective

The troublesome scaphoid fracture will heal faster and with less complications if bonegrowth stimulation through pulsed electromagnetic fields is applied directly.

Study design

6 weeks, 9 weeks, 12 weeks, 24 weeks, 52 weeks.

Intervention

Bone growth stimulation by means of pulsed electromagnetic fields (PEMF). Both arms receive a stimulator attached to their scaphoid. In one group however, the stimulator has been eliminated by the manufacturer, functioning as a placebo. Maximum intervention period is 12 weeks, depending on the healing.

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Eligibility criteria

Inclusion criteria

All unilateral scaphoid fractures, types A1, A2, B1, B2 and B3.

Exclusion criteria

1. Pregnancy;

2. Presence of a life-supporting implanted electronical device;

3. Additional fractures of wrist, carpal or metacarpal bones;

4. 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

Recruitment

NL

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

Ethics review

Positive opinion

Date:	23-10-2009

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	NL1947
NTR-old	NTR2064
Other	CMO / ABR : 2009/196 / NL27191.091.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A