The treatment of fresh scaphoid fractures with Pulsed Electromagnetic Fields (PEMF).

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The addition of PEMF to cast immobilisation in fresh scaphoid fractures will accelerate consolidation both clinically and radiologically. Possibly the incidence of non-union will be reduced.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22765

Bron
Nationaal Trial Register

Verkorte titel
N/A

Aandoening

scaphoid fractures

Ondersteuning

Primaire sponsor: Innovative Medical Devices – IMD B.V.

P.O. Box 153
5400 AD Uden
The Netherlands
Overige ondersteuning: N/A

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Consolidationn of the fracture:
at 4, 6, 12 and 24 weeks after inclusion the patients will be examined (both radiologically and physically) and will be asked to fill in the questionnaires.

Toelichting onderzoek

Achtergrond van het onderzoek

With the results of this study we want to investigate whether fresh scaphoid fractures consolidate faster when a PEMF device is used.
Studies performed by other groups show accelerated consolidation of 30 % when this non-invasive technique is used in combination with standard immobilisation. However no double blind, randomised trials have been conducted.

The aim of this study is to determine whether the use of PEMF in fresh scaphoid fractures will accelerate consolidation both clinically and radiologically, and whether the use of PEMF reduces the incidence of nonunion (for which secondary surgical intervention is needed).

Doel van het onderzoek

The addition of PEMF to cast immobilisation in fresh scaphoid fractures will accelerate consolidation both clinically and radiologically. Possibly the incidence of non-union will be reduced.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

All patients suspected of having a fresh scaphoid fracture will be treated with cast immobilisation.
Scaphoid fracture is diagnosed by a combination of physical and radiographic examination. If no apparent fracture line is seen on the initial X-rays, a Technetium scan will be performed (3-6 days after injury) to confirm the diagnosis.

The PEMF device (supplied by commercial support) will be placed on the cast within one week and will be applied for 24 hours a day continuously. The cast will be a lower arm cast with the first metacarpal bone immobilised.

Since the position of the thumb and the hand have no adverse effect on the displacement of the fracture or it’s consolidation, this neutral plaster is choosen.14,15

Half of the PEMF devices will be disabled at random in the factory. These disabled devices will give outward signs of normal function but will not generate a signal. The investigators will be unaware of the device’s functionality.
At study completion, device serial numbers will be used to determine which patients received a working device.

Follow up will take place at four, six, twelve and twenty-four weeks after diagnosis of the fractured scaphoid.
When the fracture has both clinically and radiologically consolidated the plaster will be removed.
If the fracture has not consolidated; a new plaster will be made. Only patients who need immobilisation of the fracture (not consolidated fractures) will have a PEMF device on them, for in clinically and radiographically consolidated patients there is no need for further treatment. If consolidation was established before, it can be checked at later follow up dates if that conclusion wasn’t premature. If the fracture is not consolidated after twelve weeks, at physical or radiographic examination, yet the patient has no pain the treatment is finished. If the patient has got pain, he will get a removable splint.

All tests will be compared with the opposite unaffected side. In addition to the physical and radiographic examination, patients will be required to fill in two questionnaires: an SF health survey 36 and the McGill Pain Questionnaire (multidimensional description of the patient’s feelings of pain).

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Unilateral fresh scaphoid fracture;

2. Fracture type's: A1, A2, A3, B1, B3
(Herbert Classification).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Pregnancy;

2. Presence of life supporting implanted electronical device;

3. Fracture of distal radius/ulna, the carpals or metacarpal bones;

4. Pre-existing impairment in wrist motion.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland
Status: Werving gestopt

(Verwachte) startdatum:	01-09-2005
Aantal proefpersonen:	230
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	21-08-2005
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	NL93
NTR-old	NTR124
Ander register	: N/A
ISRCTN	ISRCTN50724986

Resultaten

Samenvatting resultaten
N/A