

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

Submission date 20/12/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 20/12/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 15/07/2021	Condition category Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Individual participant data

Plain English Summary

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr B.J. van Wely

Contact details

Veemarkt 129
Nijmegen
Netherlands
6511 ZD
+31 (0)64 176 7608
bobvanwely@yahoo.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

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

Study hypothesis

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.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local medical ethics committee

Study design

Multicentre, randomised, double blind, placebo controlled, parallel group trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet**Condition**

Scaphoid fractures

Interventions

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 its consolidation, this neutral plaster is chosen.

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 devices 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 wasnt 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:

1. 36-item Short Form health survey (SF-36)
2. The McGill Pain Questionnaire (multidimensional description of the patients feelings of pain)

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Consolidation 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.

Secondary outcome measures

No secondary outcome measures

Overall study start date

01/09/2005

Overall study end date

01/09/2007

Eligibility

Participant inclusion criteria

1. Unilateral fresh scaphoid fracture
2. Fracture types: A1, A2, A3, B1, B3 (Herbert Classification)

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

230

Participant exclusion criteria

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

Recruitment start date

01/09/2005

Recruitment end date

01/09/2007

Locations

Countries of recruitment

Netherlands

Study participating centre

Veemarkt 129

Nijmegen

Netherlands

6511 ZD

Sponsor information

Organisation

Innovative Medical Devices (IMD) B.V. (The Netherlands)

Sponsor details

P.O. Box 153

Amsterdam

Netherlands

5400 AD Uden

Sponsor type

Industry

Website

<http://www.imd-eur.com/index.asp>

Funder(s)

Funder type

Not defined

Funder Name

Not provided at time of registration

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/10/2012	15/07/2021	Yes	No