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

Submission date	Recruitment status
20/12/2005	No longer recruiting
Registration date	**Overall study status**
20/12/2005	Completed
Last Edited	**Condition category**
15/07/2021	Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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 objectives
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

Health condition(s) or problem(s) studied
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 choosen.

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

Completion date
01/09/2007

Eligibility

Key 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

Key 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

Date of first enrolment
01/09/2005

Date of final enrolment
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