ISRCTN79669268 https://doi.org/10.1186/ISRCTN79669268

A pilot study: a randomised controlled trial investigating the effect of therapeutic ultrasound and exercise on active digital flexion following phalangeal fractures

Submission date
25/01/2006

Recruitment status
No longer recruiting

Registration date
01/03/2006

Overall study status
Completed

Last Edited
27/01/2009

Condition category
Injury, Occupational Diseases, Poisoning

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

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

Study objectives
Digits with fracture will have improved total active flexion following six weeks of ultrasound and a standard therapy programme when compared to digits exposed to placebo ultrasound or no ultrasound and the same programme of therapy care

Ethics approval required
Old ethics approval format

Ethics approval(s)
Added as of 18/06/2008: Nottingham Research Ethics Committee 1. Date of approval: 22/05 /2007 (ref: 06/Q2403/42)

Study design
Randomised, double-blind, placebo-controlled

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
Proximal and middle phalangeal fractures in digits 2-5

Interventions
Therapeutic ultrasound and standard hand therapy programme of care (including exercise, oedema control, splints and advice) versus placebo ultrasound and standard hand therapy programme of care.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Active digital flexion of metacarpophalangeal (MCP), interphalangeal (PIP) and distal interphalangeal (DIP) joints of the affected and contralateral finger.

Secondary outcome measures
Pain score and a measure of flexor tendon glide of affected and contralateral finger.

Overall study start date
27/02/2006

Completion date
17/07/2006

Eligibility

Key inclusion criteria
1. Closed, extra-articular, proximal or middle phalangeal fractures involving digits 2-5
2. Immobilization with a zimmer splint for 14-21 days
3. Able to attend twice-weekly therapy for six weeks
4. Over 18 years of age

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30

Key exclusion criteria
1. Compound fractures
2. Multiple fractures within the same digit
3. Intra-articular fractures and concomitant interphalangeal joint dislocations
4. Concomitant tendon injuries
5. Patients having undergone open reduction internal fixation of the fracture
6. Patients with mental impairment
7. Patients who are unable to read or understand English
8. Patients with inflammatory arthritis, significant digital osteoarthritic joint changes or diabetes
9. Patients with a pacemaker
10. Patients with carcinoma
11. Patients with previous injury to the fractured digit

12. Patients with osteoporosis
13. Patients presenting with adhered flexor tendons post-immobilization, requiring anaesthetic block

Date of first enrolment
27/02/2006

Date of final enrolment
17/07/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Physiotherapy Outpatient Department
Derby
United Kingdom
DE1 2QY

Sponsor information

Organisation
Derby University (UK)

Sponsor details
The Cedars
138 Whitaker road
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England
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DE23 6AP

Sponsor type
University/education

ROR
https://ror.org/02yhrrk59

Funder(s)

Funder type
Government

Funder Name
Trent Workforce Confederation, Derby Hospitals NHS Foundation Trust (UK)

Funder Name
Chartered Society of Physiotherapy (UK)

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