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	Prospectively registered
		Protocol
Registration date	Overall study status	Statistical analysis plan
01/03/2006	Completed	☐ Results
Last Edited	Condition category	Individual participant data
27/01/2009	Injury, Occupational Diseases, Poisoning	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Mrs Sue Kennedy

Contact details

Physiotherapy Outpatient Department Derbyshire Royal Infirmary London road Derby United Kingdom DE1 2QY

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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
Derby
England
United Kingdom
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