

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	<input type="checkbox"/> Prospectively registered
Registration date 01/03/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 27/01/2009	Condition category Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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**

United Kingdom

England

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

Sponsor information

Organisation
Derby University (UK)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration