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A pilot study comparing the effectiveness of two methods of immobilisation in the treatment of de Quervain's disease

Submission date	Recruitment status	[ ] Prospectively registered
28/09/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
28/09/2007	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
02/09/2015	Musculoskeletal Diseases	[ ] 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
N0082185031

Study information

Scientific Title
A pilot study comparing the effectiveness of two methods of immobilisation in the treatment of de Quervain's disease

Study objectives
The principal objective is to establish if increasing compliance with an immobilisation technique (by comparing removable and non-removable techniques) will produce a better clinical outcome.

The hypothesis is that by reducing patients' ability to be 'non-compliant' to the splinting regime, and immobilising the hand and wrist in a non-removable cast, the number of patients reporting ongoing symptoms at 6 week review will decrease, and the need for further immobilisation and referral for steroid injection will be reduced.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled pilot study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Musculoskeletal Diseases: De Quervain's disease

Interventions
The study consists of a pre-test post-test design, with a sample of thirty patients referred for assessment to the Hand Injuries Unit at the West Middlesex University Hospital Therapy Centre, and who are subsequently diagnosed to have de Quervain's disease. The sample will be

randomised into a treatment group of 15, for each of whom a 'non-removable' cast for hand and wrist will be applied, and a control group of 15, for each of whom a thermoplastic removable splint will be applied. Prior to immobilisation, each patient will be assessed by means of the 'Disability of the Arm and Shoulder' (DASH) assessment questionnaire, a pain scale, Finkenstein's test and the Jebsen Hand Function test. The same measures will be applied to each patient after a period of six weeks immobilisation is complete, when either the 'non-removable' cast or the thermoplastic splint, depending on which group the patient has been randomised into, will be removed. Additionally, all participants will be interviewed at 12 weeks after they enter the study and begin treatment, by a research assistant about their treatment experience and experience following treatment. The research assistant will be blinded to the treatment received by the participant and to their results.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Disability of the Arm Shoulder and Hand - measures subjective bilateral function in the upper limb in the week preceding its completion
2. Pain assessment with a modified McGill pain questionnaire, combining a visual analogue scale, word descriptors and body map indicators
3. Jebsen Hand Function test - testing gross functional dexterity
4. Finkelstein's test , of the affected tendons - indicating de Quervain's
5. Interview of participants about compliance, pain, functional impairment and treatment preferences

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/09/2006

Completion date
01/06/2007

Eligibility

Key inclusion criteria
Thirty patients who have been diagnosed as having de Quervain's disease

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
30

Key exclusion criteria
1. Patients who have already received invasive treatment including steroid injections or surgery to the first dorsal compartment of the affected hand for de Quervain's disease. These patients have already received invasive treatment and therefore conservative management is less likely to be effective. By excluding these patients we will be reducing any influencing variables and ensuring that only the effectiveness of immobilisation is being studied.
2. Patients who display a positive grind test for 1st CMC joint osteoarthritis. The nature and cause of pain in patients with a positive grind test is likely to be due to osteoarthritis of the joint and not de Quervain's disease.
3. Patients with a negative Finkelsteins test or whose pain during the test is not localised to the first dorsal compartment - as this is a diagnostic tool patients who do not display a positive Finkelsteins test are unlikely to have de Quervain's disease.
4. Patients who are unable to give informed consent or comply with the treatment regime will be excluded from this study. Hounslow PCT requires all patients to give informed consent and as this study requires participants to adhere to a protocol, all patients who are unable to do so will be excluded.
5. Patients not registered with a General Practitioner (GP). The Hand Injuries Unit requires that all patient referred to the unit are registered with a GP. This allows handover of duty of care to occur when treatment is completed. Patients who are not registered with a GP will not be assessed or receive treatment from the Hand Injuries Unit until they are registered.

Date of first enrolment
01/09/2006

Date of final enrolment
01/06/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
West Middlesex University Hospital
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Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - Department of Health

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Funder(s)

Funder type
Government

Funder Name
Hounslow Primary Care Trust

Funder Name
NHS R&D Support Funding

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