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Rheumatoid patients with wrist synovitis, if prescribed wrist splints do better in terms of grip strength, than if not prescribed

Submission date	Recruitment status	[ ] Prospectively registered
29/09/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
29/09/2006	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
26/10/2016	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

Protocol serial number
N0236177886

Study information

Scientific Title

Rheumatoid patients with wrist synovitis, if prescribed wrist splints do better in terms of grip strength, than if not prescribed

Study objectives
To explore whether the prescribing of wrist splints for wrist swelling in patients with rheumatoid arthritis, improves grip strength (function), compared to patients not prescribed splints. Wrist splints are prescribed on a daily basis in rheumatology clinics and it is not known whether there is any significant benefit obtained from their use. Hopefully the outcome of the study will provide evidence based information on the effectiveness of wrist splints for treating wrist swelling.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Not Specified

Health condition(s) or problem(s) studied
Rheumatoid arthritis (RA)

Interventions
The purpose of this research project is to explore the effectiveness of wrist splints when prescribed for swelling of the wrist. A quantitative design will be used, as the outcome will rely on numerical data statistically analysed.

The plan is to recruit 40 patients from the rheumatology clinics who will have been examined by their physician and clinically diagnosed with swelling of the wrist.

All patients eligible to take part in the study will be asked to complete the Grip Ability Test (GAT). This is a reliable and validated outcome measure to determine grip strength. The groups receiving the standard splints and the dummy splints need to be as similar as possible and so there should be equal numbers of GAT positive and GAT negative in each group.

30 patients will be randomised to receive standard rheumatoid splints and 20 patients to receive elastic dummy wrist splints. The randomisation will be achieved as follows:
Stratified randomisation: Patients will be stratified according to the outcome of the GAT test into 2 groups (GAT positive and GAT negative). Those two groups will then be assigned to treatment or dummy according to a computer generated randomisation (We have sought a statisticians advice regarding the randomisation).

The study will be a two treatment, two period, cross over study carried out over 6 months (3 months with a standard splint then 3 months with a dummy splint and vice versa).

(If after 3 months there is a statistically significant benefit from the treatment arm, the study will of course be discontinued).

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
To explore whether the prescribing of wrist splints for wrist swelling in patients with rheumatoid arthritis, improves grip strength (function), compared to patients not prescribed wrist splints.

Key secondary outcome(s))
Not provided at time of registration

Completion date
14/12/2006

Eligibility

Key inclusion criteria
1. Stable DMARDs (disease modifying anti-rheumatic drugs) for the preceding month (to ensure patients are not experiencing any known side effects to the prescribed medication)
2. Male/Female 18 years of age or over (children not seen in department)
3. Confirmed diagnosis of rheumatoid arthritis
4. Disease duration >1 year (disease process confirmed)
5. Clinically diagnosed synovitis (swelling) of the wrist
6. Able to read, understand and complete consent form and questionnaire (as the patient will be seen in clinic and expected to complete them whilst in clinic)
7. Able to wear splints as directed (as the patient will need to fit and remove splints themselves)

Patients will be attending their routine follow up rheumatology clinic and seen by their clinician. Any patient presenting with a swollen wrist who has been prescribed a wrist splint by their clinician, will be invited to speak to the researcher and the purpose of the trial fully explained. All the rheumatology clinicians in the department will be made aware of the study and will be kept informed of its progress throughout, in order to aid identification of patients.

The patients will be given the appropriate written information and asked to read whilst in clinic. The researcher will be available at that time to discuss any queries.

If the patients fully meet the criteria and have agreed to enrol on the trial they will be seen by an assistant and randomised to receive a standard splint or dummy splint.

If they are not sure, or need more time to decide, they will be able to take all the information home and will be contacted the next day for their decision.

This is to ensure that treatment is started as soon as possible regardless of whether they are involved in the trial or not.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Previous wrist or hand surgery
2. Severe deformity of the wrist or hand
3. Previous injury or fracture of the wrist or hand and disease duration < 1 year.

Date of first enrolment
28/02/2006

Date of final enrolment
14/12/2006

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
St George's NHS Trust
London
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Sponsor information

Organisation

Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Funder(s)

Funder type
Government

Funder Name
St George's Healthcare NHS Trust

Funder Name
No External Funding

Funder Name
NHS R&D Support Funding

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration