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The efficacy of wrist working splints in patients with non-destructive wrist arthritis

Submission date	Recruitment status	[ ] Prospectively registered
28/04/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
28/04/2006	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
23/09/2021	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
NL586 (NTR642)

Study information

Scientific Title
The efficacy of wrist working splints in patients with non-destructive wrist arthritis

Study objectives
We expect a reduction of pain in the wrist, measured with a Visual Analogue Scale (VAS), after 4 weeks of wrist working splint wearing, and a difference in pain score between the experimental group (splinting intervention as adjuvant to usual treatment) and the control group (usual treatment).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Rheumatoid arthritis, arthritis of the wrist

Interventions
Patients are randomly allocated to the experimental group (splinting intervention as adjuvant to usual treatment) or the control group (usual treatment). Patients in the experimental group receive a wrist working splint for their most painful hand. The splint is fitted by an occupational therapist who also gives education on splint wearing. To optimize compliance with splint wearing, compliance enhancing measures are included in this education. Patients are asked to wear the splint by day as much as possible (especially during activities) for four weeks.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Patients are measured twice: at baseline and after 4 weeks.

Primary outcome measure is pain in the wrist (VAS 0-100 mm).

Key secondary outcome(s))
1. Pain in the wrist (box scale 0-10)
2. Number of painful and swollen joints in the hand (joint count max score 11 and Ritchie scale max score 33)
3. Synovitis (ultrasound)
4. Grip strength

5. Dexterity (SODA, DASH)
6. Patient's subjective judgement about the effect of the splint on pain, swelling, grip strength and hand function

Completion date
01/10/2006

Eligibility

Key inclusion criteria
1. Diagnosis of RA according to the 1987 ACR criteria
2. Stable disease modifying anti-rheumatic drug (DMARD) therapy during preceding 3 months and no change expected for the next 4 weeks
3. Stable symptomatic therapy (non-steroidal anti-inflammatory drugs [NSAIDs] and corticosteroids) during preceding 2 weeks and no change expected for the next 4 weeks
4. Active arthritis of the wrist due to RA (clinical judgement rheumatologist)
5. Painful wrist over the past 24 hours (VAS score >35 mm)
6. Age >17 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Unable to wear a wrist splint (due to a rash, allergies etc.)
2. An injection of corticosteroid medication in the wrist or any small joints of the hand or flexor tendon sheath of the hand within the preceding 1 month or the expectation that such an injection will be indicated in the next 4 weeks
3. Carpal tunnel syndrome
4. Deformities of wrist (any [sub]luxation, any deviation) and/or fingers (e.g. MCP ulnar drifts, swan neck deformities, boutonniere deformities, subluxations thumb)
5. History of jint surgery of the wrist
6. Use of a wrist orthesis during the 2 weeks prior to participation in the study
7. Steinbrocker functional classification of 4
8. Difficulties with the Dutch language

Date of first enrolment
22/11/2005

Date of final enrolment
01/10/2006

Locations

Countries of recruitment
Netherlands

Study participating centre
University Twente
Enschede
Netherlands
7500 AE

Sponsor information

Organisation
University of Twente, Department of Psychology and Communication of Health and Risk (PCGR) (The Netherlands)

ROR
https://ror.org/006hf6230

Funder(s)

Funder type
Research organisation

Funder Name
Stichting ReumaOnderzoek Twente (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration