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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27145

Source
NTR

Brief title
N/A

Health condition

Rheumatoid arthritis (RA) patients with arthritis of the wrist.

Sponsors and support

Primary sponsor: University of Twente
Department of Psychology and Communication of Health and Risk
Source(s) of monetary or material Support: Stichting ReumaOnderzoek Twente

Intervention

Outcome measures

Primary outcome

Patients are measured twice: at baseline and after 4 weeks.

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

Secondary outcome

Secondary outcome measures are:

1. Pain in de 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.

Study description

Background summary

Wrist arthritis, which is characterized by inflammation of the wrist, is a prevalent health care problem in patients with rheumatoid arthritis (RA). Clinical features are pain and swelling. As the disease progresses, joint destruction (deformities) occur. Pain due to inflammation of the wrist or joint destruction contributes to a reduction in hand strength and a decrease in function. In the early stages of the disease, when inflammation is the most important pathophysiological phenomenon and joint destruction is at the point of occurring, conventional therapies are aimed at decreasing inflammation and pain. As adjunct to drug treatment, wrist working splints are often prescribed. This type of splint provides rest and support and stabilizes the wrist. Rest is known to reduce inflammation. So, it is supposed that in the early stages of the disease, wrist working splints could reduce local inflammation, with beneficial effects on pain and function. Although recognized by patients and health professionals these effects have never been rigorously studied.

The aim of this study is to investigate the efficacy of wrist working splints in patients with non-destructive wrist arthritis in a randomized controlled trial. Sixty patients with RA will randomly be allocated to an experimental group or a control group. Patients in the experimental group will wear a wrist working splint for 4 weeks as adjuvant to usual treatment. To improve compliance with splint wearing, compliance enhancing measures will

be included. Patients in the control group receive treatment as usual. Patients will be measured twice: at baseline and 4 weeks later. The primary outcome measure is pain in the wrist. Secondary outcome measures are: number of swollen and painful joints, synovial swelling, grip strength, and dexterity.

Study objective

We expect a reduction of pain in de wrist, measured with a Visual Analogue Scale, 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).

Study design

N/A

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

1. Diagnosis of RA according to the 1987 ACR criteria;

2. Stable DMARD therapy during preceding 3 months and no change expected for the next 4 weeks;

3. Stable symptomatic therapy (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 de past 24 hours (VAS score > 35 mm;

6. Age > 17 years.

Exclusion criteria

1. Unable to wear a wrist splint (by 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 (as there are 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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-11-2005
Enrollment:	60
Type:	Actual

Ethics review

Positive opinion

Date:	27-03-2006
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL586
NTR-old	NTR642
Other	: N/A
ISRCTN	ISRCTN22172654

Study results

Summary results
N/A