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

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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)...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27145

Bron
NTR

Verkorte titel
N/A

Aandoening

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

Ondersteuning

Primaire sponsor: University of Twente
Department of Psychology and Communication of Health and Risk
Overige ondersteuning: Stichting ReumaOnderzoek Twente

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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).

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	22-11-2005
Aantal proefpersonen:	60
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	27-03-2006
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten

N/A