

The effectiveness of finger orthoses for the treatment of swan neck deformity in arthritis patients

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| Submission date 28/12/2006 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 28/12/2006 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 14/01/2021 | Condition category Musculoskeletal Diseases | <input type="checkbox"/> Statistical analysis plan |
| | | <input checked="" type="checkbox"/> Results |
| | | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

The effectiveness of finger orthoses for the treatment of swan neck deformity in arthritis patients

Acronym

EFFORT

Study objectives

Oval-8 splints and Silver Ring splints are equally effective in improving dexterity in patients with swan neck deformities in index-and middle finger

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval received from the Ethics board of Leiden University Medical Center on the 28th February 2005 (ref: P05.011).

Study design

Randomised, controlled, multicentre trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Rheumatoid diseases with hand involvement

Interventions

- A. Intervention with a Silver Ring splint
- B. Intervention with a Oval-8 splint

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Dexterity:

1. Hand/finger function domain of the Arthritis Impact Measurements Scales
2. Sequential Occupational Dexterity Assessment score.

Secondary outcome measures

1. Motivation
2. Expectations, preferences and acceptability
3. Compliance and costs

Overall study start date

01/03/2005

Completion date

31/12/2006

Eligibility

Key inclusion criteria

1. Mobile swanneck deformity on digits two and/or three due to rheumatoid disease
2. Adults
3. Stable disease activity

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

50

Total final enrolment

50

Key exclusion criteria

1. Not a good understanding of the Dutch language
2. Already using swan neck orthoses
3. Conditions that prohibit the use of orthoses
4. Other diseases with effect on hand function

Date of first enrolment

01/03/2005

Date of final enrolment

31/12/2006

Locations

Countries of recruitment

Netherlands

Study participating centre

Leiden University Medical Center (LUMC)

Leiden

Netherlands

2300 RC

Sponsor information

Organisation

Leiden University Medical Center (LUMC) (The Netherlands)

Sponsor details

Department of Rheumatology

P.O. Box 9600

Leiden

Netherlands

2300 RC

Sponsor type

Hospital/treatment centre

Website

http://www.lumc.nl/english/start_english.html

ROR

<https://ror.org/05xvt9f17>

Funder(s)

Funder type

Research organisation

Funder Name

Dutch Arthritis Association (Reumafonds) (The Netherlands)

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

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------------------|--------------|------------|----------------|-----------------|
| Results article | qualitative results | 01/12/2010 | 14/01/2021 | Yes | No |
| Results article | results | 15/08/2009 | 14/01/2021 | Yes | No |