

# Effect of orthoses in hand osteoarthritis

<b>Submission date</b> 03/11/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 11/12/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 27/08/2014	<b>Condition category</b> 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**  
Dr Ingvild Kjekken

**Contact details**  
Diakonhjemmet Hospital  
Boks 23 Vinderen  
Oslo  
Norway  
0319  
+47 22 45 48 45  
ingvild.kjekken@diakonsyk.no

## Additional identifiers

**Protocol serial number**  
N/A

## Study information

**Scientific Title**  
Effect of prefabricated orthoses for persons with osteoarthritis of the carpometacarpal joint: a randomised controlled trial

**Acronym**  
HandOAorthoses

## **Study objectives**

Primary question:

Is the use of prefabricated orthoses combined with hand exercises more effective to relieve pain and improve hand function in persons with osteoarthritis in the carpometacarpal (CMC1) joint, than hand exercises alone?

Secondary question:

Is the use of prefabricated orthoses combined with hand exercises more effective to increase hand strength in persons with osteoarthritis in the CMC1 joint, than hand exercises alone?

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Ethical Committee for Medical Research, 24/09/2008, ref: 413-08-00056, and the Norwegian Data Inspectorate

## **Study design**

Randomised controlled trial

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Osteoarthritis of the carpometacarpal joint

## **Interventions**

Provision of orthoses:

Participants in group 1 are provided with a prefabricated orthosis, aimed at giving support to the CMC1 joint. Participants with an adduction contracture are offered a custom-made orthosis to wear routinely at night.

Hand exercises:

All participants (group 1 and group 2) are instructed in four basic hand exercises, aimed at improving or maintaining joint mobility, joint stability and hand strength. They are given a leaflet with descriptions and pictures of the exercises, and instructed to perform the exercises twice a day.

Patients in group 2 will be offered orthoses at two months follow-up.

## **Intervention Type**

Other

## **Phase**

Not Specified

## **Primary outcome(s)**

Assessed at baseline and after two months:

1. Hand pain measured on visual analogue scales
2. Function in performance of daily activities, measured by the MAP-hand

### **Key secondary outcome(s)**

Assessed at baseline and after two months:

1. Hand strength, measured with the Grippit
2. Hand function, measured with the pain, stiffness and function subscales of the Australian /Canadian hand osteoarthritis measure (AUSCAN)
3. Abduction of the thumb, measured with Gripsizer
4. Patient-acceptable symptoms, measured with the Patient Acceptable Symptom State (PASS)
5. General function, measured with the Modified Health Questionnaire (MHAQ)
6. Quality of life, European Quality of Life questionnaire (EuroQoL EQ-5D)
7. Self-efficacy in relation to pain, measured with the Arthritis Self Efficacy Pain Subscale

Assessed after two months only:

8. Costs
9. Participants' experiences with prefabricated orthoses and hand exercises (structured interview with participants in group 1)

### **Completion date**

31/12/2010

## **Eligibility**

### **Key inclusion criteria**

1. Aged from 18 to 75 years, either sex
2. Hand osteoarthritis
3. Pain in the carpometacarpal joint
4. Ability to communicate in Norwegian

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Sex**

All

### **Key exclusion criteria**

1. Cognitive impairment or mental disease
2. Past surgery of the thumb
3. Impaired hand function due to other diseases
4. Steroid injections within the last month

**Date of first enrolment**

15/11/2008

**Date of final enrolment**

31/12/2010

## Locations

**Countries of recruitment**

Norway

**Study participating centre**

Diakonhjemmet Hospital

Oslo

Norway

0319

## Sponsor information

**Organisation**

Diakonhjemmet Hospital (Norway)

**ROR**

<https://ror.org/02jvh3a15>

## Funder(s)

**Funder type**

Research organisation

**Funder Name**

National Resource Centre for Rehabilitation in Rheumatology (Norway)

**Funder Name**

Norwegian Association of Occupational Therapists (Norsk Ergoterapeutforbund [NETF])  
(Norway)

## Results and Publications

### 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?
<a href="#">Results article</a>	results	01/01/2014		Yes	No