ISRCTN40357804 https://doi.org/10.1186/ISRCTN40357804

Effect of orthoses in hand osteoarthritis

Submission date 03/11/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 11/12/2008	**Overall study status** Completed	
Last Edited 27/08/2014	**Condition category** Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Ingvild Kjeken

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

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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

Secondary outcome measures
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)

Overall study start date
15/11/2008

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

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)

Sponsor details
Boks 23 Vinderen
Oslo

Norway
0319
+47 22 45 15 00
firmapost@diakonsyk.no

Sponsor type
Hospital/treatment centre

Website
http://www.diakonsyk.no

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

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	results	01/01/2014		Yes	No