# Hypoalgesic and motor effects of Kaltenborn mobilization on elderly patients with secondary thumb carpometacarpal osteoarthritis

Submission date	Recruitment status	[X] Prospectively registered
15/05/2011	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
26/05/2011	Completed	Results
Last Edited	Condition category	Individual participant data
30/06/2017	Musculoskeletal Diseases	Record updated in last year

#### Plain English summary of protocol

Background and study aims

Osteoarthritis is a condition that causes joints to become painful and stiff, such as the carpometacarpal (CMC) joint of the thumb. The main cause of thumb CMC osteoarthritis is deterioration of the surfaces of the joint and abnormal bone growth. CMC osteoarthritis mainly affects women after the menopause, and often requires surgical treatments. Kaltenborn manual therapy is based on the concept of mobilization with general movement. Human joint surfaces are not fully congruent; therefore, physiological movements are a combination of a rotation and a glide. Distraction mobilization techniques are frequently performed on joints of the extremities, spine and jaw to assess the joint or as treatment to relieve pain or maintain or improve joint mobility. The aim of this study is to find out whether Kaltenborn manual therapy relieves pain and increases strength in CMC osteoarthritis patients.

Who can participate? Patients aged 70–90 with CMC osteoarthritis

#### What does the study involve?

Participants are randomly allocated to either the Kaltenborn manual therapy or placebo (sham treatment) group. Kaltenborn manual therapy consists of glide mobilization of the dominant hand during six sessions over two weeks. Participants in the placebo group attend the same number of sessions as those in the Kaltenborn group, but they receive intermittent ultrasound treatment for 10 minutes each to the thumb region (sham treatment). Pain, pinch strength and grip strength are measured before treatment and after one and two weeks.

What are the possible benefits and risks of participating? Not provided at time of registration

Where is the study run from? Azienda Sanitaria Locale (ASL) 3 (Italy) When is the study starting and how long is it expected to run for? May 2011 to June 2011

Who is funding the study? Investigator initiated and funded (Italy)

Who is the main contact? Dr Jorge Villafañe

# Contact information

# Type(s)

Scientific

#### Contact name

Dr Jorge Villafañe

#### Contact details

Via C. Colombo 2/9 Piossasco Italy 10045

# Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

**Secondary identifying numbers** N/A

# Study information

#### Scientific Title

Hypoalgesic and motor effects of Kaltenborn mobilization on elderly patients with secondary thumb carpometacarpal osteoarthritis: a randomized, controlled trial

### Study objectives

The thumb assumes 50% of the hand function, and the carpometacarpal (CMC) joint is the most important of its osteoarticular complex. Carpometacarpal osteoarthritis (CMC OA) is a degenerative alteration of the CMC OA that is characterized by abrasion, progressive deterioration of the joint surfaces and new bone formation at the site of deterioration. The impact of this pathology is the functional deficit that it causes in its most severe form. CMC OA is a process that affects mainly postmenopausal women, and at present, it is considered the upper limb osteoarthritis that causes of most surgical treatments.

The aim of this study is to determine whether specific Kaltenborn mobilization of posterioranterior gliding with distraction of the carpometacarpal (CMC) joint decreases mechanical hyperalgesia and increase the strength of the tip pinch and tripod pinch in patients with secondary carpometacarpal osteoarthritis in the dominant hand.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Local Health Authority, Collegno, Italy (Residenze Sanitarie Assistenziali Azienda Sanitaria Locale 3 (A.S.L 3), Collegno Italy) 12/10/2008

#### Study design

Randomized 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 to request a patient information sheet

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

Carpometacarpal osteoarthritis

#### **Interventions**

Kaltenborns mobilization technique:

In brief, Kaltenborn described these mechanics in terms of the convex-concave rule. The direction of decreased joint gliding in a hypomobile joint and thus the appropriate treatment can be deduced by this rule. With movement of a concave joint partner, the glide occurs in the same direction. The form of the joint surface has been considered to induce its gliding/sliding movement; a female (concave) joint surface glides in the same direction as the bone movement while a male (convex) surface glides in the opposite direction of the bone movement. Traction is the technique that distracts one articular surface perpendicular to the other, and the glide technique describes the translational gliding of one articular surface parallel to the other.

- 1. We used the specific Kaltenborn mobilization of posterior-anterior gliding with distraction of the carpometacarpal (CMC) joint
- 2. The Convex/Concave Rule was applied in each case
- 3. The subject is seated with his arm in the anatomic position, the elbow at 90° flexion, and the forearm and hand with the cubital face downwards and the dorsal face against the body of the

#### physiotherapist

- 4. The physiotherapist takes the right thumb metacarpal bone of the subject with his right thumb and index finger and makes a specific Kaltenborns mobilization of posterior-anterior gliding of a short amplitude with distraction of the CMC joint for 3 minutes with a 1 minute pause. The action is repeated three times.
- 5. The physiotherapist distracts the joint retracting from the thumb and glides the first metacarpal bone in a posterior-anterior orientation
- 6. In the posterior-anterior gliding movement of the first metacarpal bone, the head and body must slide in the same way because the articular surface of the trapezium is convex and the surface of the first metacarpal bone is concave
- 7. The gliding movement respects the rule of convexity-concavity of the joint

#### Placebo technique:

1. Participants in the placebo group attended the same number of sessions as did those in the Kaltenborn mobilization group, but they received intermittent ultrasound therapy for 10 minutes each that was non-therapeutic to the thumb region

#### Intervention Type

Other

#### Phase

Not Applicable

#### Primary outcome measure

- 1. Pain measurement
- 1.1. Pressure pain threshold (PPT) was measured by using a mechanical pressure algometer (Wagner Instruments, Greenwich, Connecticut, USA) with a 1cm2 rubber tipped plunger mounted on a force transducer
- 1.2. The PPT is defined as the minimum amount of pressure that results in the sense of pressure changing to pain
- 1.3. The mean of three measurements (intra-examiner reliability) was calculated and used for the main analysis
- 1.4. The range of values of the pressure algometer was 0 to 10 kg, with a minimal sensibility of 0.1 kg
- 1.5. For these specific cases, the algometry has higher reliability (Intra-class correlation coefficient [ICC]=0.91, Interval confidence [IC] del 95%: 0.82-0.97) for PPT measurement in older patients
- 1.6. In addition, previous studies have reported an intra-examiner reliability for this procedure ranging from 0.6 to 0.97, and the inter-examiner reliability ranged from 0.4 to 0.98
- 1.7. PPT measurements were collected at both thecarpometacarpal (CMC) joint at the bottom of the anatomical snuffbox and tubercle of the scaphoid bone
- 2. Strength measurements:
- 2.1. Pinch strength:
- 2.1.1. The pinch strength was measured by a mechanical pinch gauge (Baseline, NY, USA) while the patient was in the sitting position with the shoulder adducted and neutrally rotated and the elbow flexed at 90°
- 2.1.2. Two different measurements were taken: first, the tip pinch between the index finger and thumb and, then, the tripod pinch between the index and medial fingers and the thumb 2.1.3. The reliability of this procedure to measure the pinch strength has been found to be on the order of 0.93
- 2.2. Grip strength measurements:

- 2.2.1. Grip strength measurements were taken with a grip dynamometer (Baseline, NY, USA) while the patient was also in the sitting position, which has a precision and reliability of  $\pm$  3% for grip strength measurements
- 2.2.2. The reliability of the measurements was expressed by ICC between 0.82 and 0.97 for grip strength measurements

#### Secondary outcome measures

No secondary outcome measures

#### Overall study start date

30/05/2011

#### Completion date

30/06/2011

# **Eligibility**

#### Key inclusion criteria

Patients who used the dominant hand systematically such as ex-factory workers and home workers, and were diagnosed with secondary carpometacarpal osteoarthritis in the dominant hand by X-ray detection of stage III and IV according to the Eaton-Littler-Burton Classification

#### Participant type(s)

Patient

#### Age group

Senior

#### Sex

Both

#### Target number of participants

29 patients

#### Key exclusion criteria

- 1. With a medical history of carpal tunnel syndrome
- 2. Arthritis
- 3. Surgical interventions on CMC joint
- 4. Patients with DQuervains tenosynovitis were also excluded
- 5. Patients presenting degenerative or non-degenerative neurological conditions in which pain perception was altered

#### Date of first enrolment

30/05/2011

#### Date of final enrolment

30/06/2011

# Locations

#### Countries of recruitment

Italy

Study participating centre Via C. Colombo 2/9

Piossasco Italy 10045

# Sponsor information

#### Organisation

Azienda Sanitaria Locale (ASL) 3 (Italy)

#### Sponsor details

c/o Jorge Hugo Villafane Via C. colombo 2/9 Collegno Italy 10093

#### Sponsor type

Hospital/treatment centre

#### Organisation

Rey Juan Carlos University (Universidad Rey Juan Carlos)

#### Sponsor details

Department of Physical Therapy, Occupational Therapy, Rehabilitation and Physical Medicine Alcorcón Spain

- -

#### Sponsor type

University/education

#### Organisation

Azienda Sanitaria Locale

#### Sponsor details

Sponsor type

#### Not defined

#### Website

http://www.aslromad.it/

#### **ROR**

https://ror.org/05xcney74

# Funder(s)

## Funder type

Other

#### Funder Name

Investigator initiated and funded (Italy)

# **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