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Bilateral sensory and motor effects of unilateral combined treatment in patients with carpo-metacarpal osteoarthritis

Submission date
04/08/2012

Recruitment status
No longer recruiting

Registration date
09/08/2012

Overall study status
Completed

Last Edited
17/12/2020

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

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. Thumb CMC osteoarthritis is a common condition after the age of 50, especially in women. The main cause of thumb CMC osteoarthritis is deterioration of the surfaces of the joint and abnormal bone growth, which results in pain at the base of the thumb. The aim of this study is to assess changes in the pressure sensitivity and pinch grip force of patients with thumb CMC osteoarthritis after mobilization of the affected hand.

Who can participate?
Patients aged 65–90 with CMC osteoarthritis

What does the study involve?
Participants are randomly allocated into either the combined treatment group or the placebo (dummy treatment) group. The combined treatment consists of Kaltenborn, radial and median nerve mobilization and hand exercises of the dominant hand during 12 sessions over 4 weeks. Participants in the placebo group attend the same number of sessions as those in the combined treatment group, but they receive ultrasound therapy for 10 minutes on the affected hand. Pain, pinch strength and grip strength are measured before treatment and after 1 month and 2 months.

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

Where is the study run from?
Local Health Authority, Collegno (Italy)

When is the study starting and how long is it expected to run for?
January 2012 to April 2012

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

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Bilateral sensory and motor effects of unilateral combined treatment in patients with carpo-metacarpal osteoarthritis: a randomized clinical trial

Study objectives
Thumb carpo-metacarpal (CMC) osteoarthritis (OA) is a common condition after the age of 50, especially in female. The main cause of thumb CMC OA is a degenerative progressive alteration of the thumb CMC joint. This degeneration includes chronic deterioration of superficial surfaces of the joint and ectopic bone regeneration, which results in pain at the base of the thumb.

Central sensitization is defined as an intensification of the responsiveness of central pain-signaling neurons from low-threshold mechanoreceptors. Central sensitization includes changes

in sensory processing and down regulation of descending pain-inhibitory mechanisms. The importance of central sensitization processes underlies a mechanism of pain in OA pain which has recently gained interest.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local Health Authority, Collegno, Italy [Residenze Sanitarie Assistenziali Azienda Sanitaria Locale], 10/12/2008, ref: 93571/c

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
Thumb carpo-metacarpal osteoarthritis

Interventions
Treatment group

Kaltenborn mobilization:
1. The therapist grasps the right thumb metacarpal bone of the patient with his right thumb-index fingers
2. The therapist distracts the joint retracting the thumb and gliding the first metacarpal bone in a posterior-anterior direction
3. A posterior-anterior gliding of short amplitude with distraction of the thumb CMC joint was applied for 3 minutes with a 1 minute pause
4. The mobilization sequence was repeated 3 times

Median nerve mobilization.
1. The patient was positioned in supine and the therapist was seated
2. The physical therapist induces shoulder girdle depression, gleno-humeral abduction and lateral rotation, supination of the forearm, wrist, thumb, and finger extension of the patients arm
3. The slider neurodynamic technique of the median nerve consists of alternation of elbow

extension (loads the median nerve) and wrist flexion (unloads the median nerve), with elbow flexion (unloading) and wrist extension (loading)
4. The range of motion was: wrist 0-60° extension; elbow 90-165° extension depending on the tissue resistance
5. The slider intervention was completed over 5-10 minutes in two sets of 5min each with 1min rest between sets
6. Speed and amplitude of movement were adjusted such that no pain was produced during the technique

Radial nerve mobilization:
1. Treatment was performed in six sessions over four weeks and was applied to the dominant hand three times during a four-minute period with one-minute pauses between periods
2. The technique consisted of a sliding mobilization of the proximal-distal radial nerve
3. To begin the technique, the patient was positioned in supine and the physiotherapist was seated
4. The physiotherapist depressed the patients shoulder girdle, extended the patients elbow and then internally rotated the arm
5. The patients wrist, thumb and all the fingers were flexed. Finally ulnar deviation of the hand was added
6. This combination of movements is hypothesized to cause stress the radial nerve
7. Once the upper extremity was positioned two movements were done as follows:
7.1. Soulder depression was applied simultaneously with elbow flexion and wrist extension
7.2. Shoulder elevation is performed with elbow extension and wrist flexion and ulnar deviation
8. These motions are alternated at a rate of approximately 2 seconds per cycle (1 second into extension and 1 second into flexion)

Hand Exercises:
The first six exercises consisted of active range of motion movements of the hand designed to improve joint flexibility. The last three exercises were designed to strengthen grip and pinch grips by using a non-latex polymer ball: the Thera-Band Hand Exerciser (The Hygenic Corporation, Akron, OH). The hand exerciser is color coded by approximate resistance level at 50% compression, with yellow at 0.68 kg, red at 1.36 kg, green at 2.27 kg, and blue at 3.64 kg.

Placebo technique (control):
1. Participants in the placebo group attended the same number of sessions as those in the treatment group, but they received intermittent ultrasound therapy for 10 minutes with an intensity of 0 watts/cm^2 to on the hypothenar area of the dominant hand
2. Gel was used as required

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Mechanical pain sensitivity:
1.1. Pain sensitivity was determined by measuring pressure pain threshold (PPT)
1.2. Measurements were performed with a Mechanical Pressure Algometer (Wagner Instruments, Greenwich, Connecticut, USA) with a 1cm2 rubber-tipped plunger mounted on a force transducer was used for measuring PPT

1.3. Pressure was applied at a rate of 30 kPa/s
1.4. The mean of three measurements was calculated and used for the main analysis
1.5. Previous papers have reported an intraexaminer reliability of this procedure ranging from 0.6 to 0.97, while the interexaminer reliability ranged from 0.4 to 0.98
1.6. The following points were evaluated:
1.6.1. TM joint at the bottom of the anatomical snuffbox, tubercle of the scaphoid bone and unciform apophysis of the hamate bone
1.6.2. Three measurements were made with a one-minute pause between them
1.6.3. Although pain from deep tissue is difficult to assess precisely, PPT have been found useful in assessing pain reactions in OA patients
2. Pain evaluation:
2.1. The main outcome of the study was pain intensity
2.2. The intensity of thumb CMC joint pain was assessed with a 100mm visual analogue scale (VAS)
2.3. The VAS is a 100mm line anchored with a 0 at one end representing no pain and 100 at the other end representing the worst pain imaginable.
2.4. The VAS was selected as the main outcome measure based on its ability to detect changes with a minimal clinically important difference (MCID) ranging from 9 to 11 mm
3. Motor performance:
3.1. Pinch strength
3.1.1. The pinch strength was evaluated with a mechanical pinch gauge (Baseline, NY, USA) in the sitting position with the shoulder adducted and neutrally rotated and the elbow flexed at 90°
3.1.2. Two different measurements were taken. First the tip pinch between index and thumb fingers is measured. Then the tripod pinch, between index and, middle fingers and the thumb is measured
3.1.3. The reliability of pinch strength has been found to be high (Intra-class correlation coefficient [ICC]= 0.93)
3.2. Grip strength
3.2.1. Grip strength was assessed with a grip dynamometer (Baseline, NY, USA) with the patient in the sitting position
3.2.2. This procedure has shown to have a precision of ± 3% (15-17)
3.2.3. The reliability of grip strength has been reported to be high (ICC: 0.82- 0.97)

Measurements were taken before intervention and after 1 and 2 months.

Secondary outcome measures

1. The Beck Depression Inventory (BDI)
1.1. Review of internal consistency for the BDI ranges from 0.73 to 0.92, with a mean of 0.86, with alpha coefficients of 0.86 and 0.81 for psychiatric and non-psychiatric populations, respectively
1.2. The BDI observed showed high discrimination of depressive symptoms (75-100%)
2. State-Trait Anxiety Inventory (STAI)
2.1. This is a self rated questionnaire divided in two parts: anxiety-trait (referring to personality aspects) and anxiety-state (referring to systemic aspects of the context)
2.2. Responses are in a 1-4 scale
2.3. Anxiety-state refers to how individuals feel at the moment and anxiety-trait to how they generally feel
2.4. Each part varies from 20 to 80 points, and the scores indicate low (0-30), medium (31-49) or high (50 or more) anxiety levels

Measurements were taken before intervention and after 1 and 2 months.

Overall study start date
16/01/2012

Completion date
14/04/2012

Eligibility

Key inclusion criteria
1. Patients who used the dominant hand systematically such as ex-factory workers and home workers
2. Diagnosed with secondary thumb carpometacarpal osteoarthritis (CMC OA) 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
Adult

Sex
Both

Target number of participants
60

Total final enrolment
60

Key exclusion criteria
1. Patients if they scored more than 4 on the Becks Depression Inventory and/or more than 30 on the State Trait Anxiety Inventory (STAI)
2. Patients with a medical history of carpal tunnel syndrome, arthritis, surgical interventions on the thumb CMC joint, or DQuervains tenosynovitis
3. Patients presenting degenerative or non-degenerative neurological conditions in which pain perception was altered

Date of first enrolment
16/01/2012

Date of final enrolment
14/04/2012

Locations

Countries of recruitment
Italy

Study participating centre
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Sponsor information

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Sponsor type
Government

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2013	17/12/2020	Yes	No