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Randomised controlled trial for the treatment of hand arthrosis with prednisolone and naproxen

Submission date	Recruitment status	[ ] Prospectively registered
23/11/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
10/03/2006	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
13/03/2006	Musculoskeletal Diseases	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

IDS 04-05

Study information

Scientific Title

Acronym
BELIOA2

Study objectives
The primary hypothesis is that patients with hand arthrosis treated with prednisolone for one week (3 days 50 mg, 4 days 25 mg) will improve significantly in different clinical parameters

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study was approved by the Internal Review Board and Ethical Committee of the Vienna Medical University on 14/02/2006, reference number 481/2005

Study design
Single-centre, randomised, double-blind, placebo-controlled clinical 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
Hand arthrosis

Interventions
Patients are randomised to receive treatment with either prednisolone or naproxen or placebo

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Prednisolone and naproxen

Primary outcome measure
Pain in the target hand measured on a 100 mm VAS

Secondary outcome measures
1. Morning stiffness
2. VAS for disease activity
3. Tender and swollen joint counts (inflammatory and bony swelling)
4. Functioning measured with:
a. Health Assessment Questionnaire (HAQ)
b. Score for Assessment and Quantification of Chronic Rheumatic Affections of the Hands (SACRAH)
c. Arthritis Impact Measurement Scales 2 - Short Form (AIMS2-SF)
d. Grip strength
e. Moberg picking-up test

Overall study start date
01/12/2005

Completion date
01/12/2006

Eligibility

Key inclusion criteria
1. Hand arthrosis
2. Age over 18 years
3. Pain on a 100 mm Visual Analogue Scale (VAS) in the target hand more than 40 mm
4. Willingness to comply with the protocol

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
246

Key exclusion criteria
1. Current treatment with steroids
2. Cardiac insufficiency

3. Infection
4. Uncontrolled hypertension
5. History of gastrointestinal bleeding
6. Diabetes mellitus
7. Allergy against study medication
8. Pregnancy

Date of first enrolment
01/12/2005

Date of final enrolment
01/12/2006

Locations

Countries of recruitment
Austria

Study participating centre
Department of Internal Medicine III
Vienna
Austria
A-1090

Sponsor information

Organisation
Vienna Medical University (Austria)

Sponsor details
Department of Internal Medicine III
Division of Rheumatology
Wahringer Gurtel 18-20
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Sponsor type
University/education

ROR
https://ror.org/05n3x4p02

Funder(s)

Funder type
University/education

Funder Name
Vienna Medical University (Austria)

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