

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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof Josef Smolen

Contact details

Department of Internal Medicine III

Division of Rheumatology

Wahringer Gurtel 18-20

Vienna

Austria

A-1090

+43 (0)140 400 4381

josef.smolen@wienkav.at

Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

Pain in the target hand measured on a 100 mm VAS

Key secondary outcome(s))

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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)

ROR
<https://ror.org/05n3x4p02>

Funder(s)

Funder type
University/education

Funder Name
Vienna Medical University (Austria)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration