

Randomised double blind trial of prednisone and naproxen in treatment of crystal proven acute gout

Submission date 20/12/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 20/12/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 03/06/2008	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title

Acronym

PREDJ-study (PREDnison Jicht = gout)

Study objectives

Active treatment of acute gouty arthritis by a short course of oral prednisone or naproxen are equal.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local medical ethics committee

Study design

Randomised, double blind, active controlled, parallel group trial.

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Acute gout

Interventions

Five days, by oral administration, either prednisolone 35 mg (= 30 mg prednisone) once a day or naproxen at a dose of 500 mg twice a day. Patients received blind capsules containing active prednisolone and placebo naproxen, or active naproxen and placebo prednisolone.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Prednisone, naproxen

Primary outcome(s)

Patient assessment of pain in the study joint, indicated on visual analogical scales two times a day, during 4 days.

Key secondary outcome(s)

1. Patients global disability
2. The walking disability, if the study joint was in the leg or foot
3. Safety and tolerability of prednisone versus naproxen

Completion date

01/06/2006

Eligibility

Key inclusion criteria

All patients referred to the rheumatology department of one hospital, by their general practitioner because of mono-arthritis, who proved to have urate crystals after diagnostic joint aspiration.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Key exclusion criteria

1. Use of anti-trombolytica
2. A history of peptic ulcer
3. A history of reduced renal function
4. A history of heart failure
5. A known hypersensitivity to naproxen and/or prednisone
6. Use of any Non-Steroidal Anti-Inflammatory Drug (NSAID) or prednisone within the past 12 hours
7. Unwillingness to participate

Date of first enrolment

01/04/2004

Date of final enrolment

01/06/2006

Locations

Countries of recruitment

Netherlands

Study participating centre

Department of General Practice and Family Medicine

Nijmegen

Netherlands

6500 HB

Sponsor information

Organisation

University Medical Center St. Radboud (The Netherlands)

ROR

<https://ror.org/05wg1m734>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

University Medical Center St. Radboud (The Netherlands)

Results and Publications

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	31/05/2008		Yes	No