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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

Registration date
20/12/2005

Overall study status
Completed

Last Edited
03/06/2008

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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

Secondary outcome measures
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

Overall study start date
01/04/2004

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

Age group
Not Specified

Sex
Not Specified

Target number of participants
120

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)

Sponsor details
Department of General Practice and Family Medicine
P.O. Box 9101
Nijmegen
Netherlands
6500 HB

Sponsor type
Hospital/treatment centre

Website
http://www.umcn.nl/homepage

ROR
https://ror.org/05wg1m734

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Medical Center St. Radboud (The Netherlands)

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	31/05/2008		Yes	No