

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

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON29462

### Source

NTR

### Brief title

PREDJ-study (PREDnison Jicht = gout)

### Health condition

Acute gout.

## Sponsors and support

**Primary sponsor:** No competing interests

**Source(s) of monetary or material Support:** N/A

## Intervention

## Outcome measures

### Primary outcome

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

## Secondary outcome

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.

## Study description

### Background summary

The primary objective of this study. We want try to assess the efficacy and safety of a short course oral prednisone in the treatment of (crystal proven) acute gout. Naproxen, a non-steroidal anti-inflammatory drug (NSAID), which is prescribed frequently for acute gout with proven effect, will be used as index therapy.

Possible benefit of the study. In literature we could not find important side effects and contra-indications from a short course with prednisone. If prednisone should be equal to naproxen in our study, a cheap drug occurs, to treat acute gout, as alternative to NSAIDs. NSAIDs have well known side effects and contra-indications (gastro-intestinal, cardiologic, nephrologic), especially in middle aged and older people. Gout patients are mostly middle aged or older, and are often suffering from cardiologic and nephrologic problems. Hence, they could have benefits from prednisone, as an alternative to NSAIDs.

Participants of our study are gout patients referred by family physicians, who diagnose and treat the most gout patients in normal medical practice.

### Study objective

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

### Study design

N/A

### Intervention

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

## Contacts

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## Eligibility criteria

### **Inclusion criteria**

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

### **Exclusion criteria**

1. Use of anti-trombolytica;
2. A history of peptic ulcera;
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 NSAID or prednisone within the past 12 hours;
7. Unwillingness to participate.

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-2004
Enrollment:	120
Type:	Actual

## Ethics review

Positive opinion	
Date:	14-08-2005
Application type:	First submission

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

Register	ID
NTR-new	NL92
NTR-old	NTR123
Other	: N/A
ISRCTN	ISRCTN14648181

## Study results

### Summary results

1. Janssens HJEM, van de Lisdonk EH, Janssen M, van den Hoogen HJM, Verbeek ALM. Gout, not induced by diuretics. A case-referent study from primary care. Ann Rheum Dis 2005. Offered for publication; being reviewed. <br>
2. Janssens HJEM, van de Lisdonk EH, Bor H, van den Hoogen HJM, Janssen M. Gout, just a nasty event or a cardiovascular signal? A study from primary care. Fam Pract 2003;20:413-6. <br>
3. Janssens HJEM. De standaard 'Jicht' van het Nederlands Huisartsen Genootschap; reactie vanuit de huisartsgeneeskunde. Ned Tijdschr Geneeskd 2002;146:292-4. Commentaar: Ned Tijdschr Geneeskd 2002;146:872-3.