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# A randomized, controlled study of intra-articular injections of etanercept or glucocorticosteroids in patients with rheumatoid arthritis

**Submission date**
15/07/2005

**Recruitment status**
No longer recruiting

**Registration date**
19/07/2005

**Overall study status**
Completed

**Last Edited**
05/11/2008

**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

**Protocol serial number**
KF 02-064/02

## Study information

## Scientific Title

## Study objectives
Etanercept is more efficient than glucocorticosteroid for the treatment of synovitis when given intra-articularly

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Not provided at time of registration

## Study design
Randomised controlled trial

## Primary study design
Interventional

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Rheumatoid arthritis

## Interventions
Intra-articular injection of
1. 25 mg Etanercept
2. 40 mg methylprednisolone

## Intervention Type
Drug

## Phase
Not Specified

## Drug/device/biological/vaccine name(s)
Etanercept, glucocorticosteroid

## Primary outcome(s)
1. Patient global evaluation of the joint treated
2. Independent joint evaluation by investigator

## Key secondary outcome(s))
Clinical: Joint score for swelling and tenderness and HAQ, CRP, ESR, grip strength
Imaging:
Ultrasound Doppler pixel fraction
Ultrasound Doppler RI
Postcontrast magnetic resonance imaging (MRI)

### Completion date
31/12/2004

## Eligibility

### Key inclusion criteria
Rheumatoid arthritis (RA), age >18 years, written informed consent, flare of RA in wrist, elbow, or knee joint

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
All

### Key exclusion criteria
Systemic anti tumour necrosis factor (TNF) alpha therapy, had had intra-articular injection of steroids in the joint within 3 months, had skin lesions or other disease associated with increased risk of infection after injection, malignancy, severe heart, kidney, and/or lung disease, infections including human immunodeficiency virus (HIV), elevated alanine aminotransferase (ALT) (twice above the reference range), creatinine (>175 mmol/l), leucopenia (<3.5 x 10^9/l), thrombocytopenia (<125 x 10^9/l), or hemoglobin <8.5 g/dl, or allergy to the injected compounds. Women were excluded if pregnant, or of childbearing potential with an unacceptable birth control method.

### Date of first enrolment
01/09/2003

### Date of final enrolment
31/12/2004

## Locations

### Countries of recruitment
Denmark

### Study participating centre
**The Parker Institute**
Frederiksberg

Denmark
DK 2000

# Sponsor information

**Organisation**
The Parker Institute (Denmark)

**ROR**
https://ror.org/05bpbnx46

# Funder(s)

**Funder type**
Industry

**Funder Name**
Core grant from the Oak Foundation No. OUSA-01-030 (USA)

**Funder Name**
Wyeth Inc. No. 0881A-101299 (USA)

# 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 | 01/09/2006 | | Yes | No |