

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

<b>Submission date</b> 15/07/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 19/07/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 05/11/2008	<b>Condition category</b> 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**  
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 ( $<3.5 \times 10^9/l$ ), thrombocytopenia ( $<125 \times 10^9/l$ ), 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?
<a href="#">Results article</a>	results	01/09/2006		Yes	No