

# 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

### Contact name

Prof Henning Bliddal

### Contact details

The Parker Institute  
Frederiksberg Hospital  
Frederiksberg  
Denmark  
DK 2000  
+45 38164151  
[henning.bliddal@fh.hosp.dk](mailto:henning.bliddal@fh.hosp.dk)

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

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

### 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

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 measure**

1. Patient global evaluation of the joint treated
2. Independent joint evaluation by investigator

**Secondary outcome measures**

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)

**Overall study start date**

01/09/2003

**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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

38

**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)

**Sponsor details**

Frederiksberg Hospital

Ndr Fasanvej 57

Frederiksberg

Denmark

DK 2000

**Sponsor type**

Research organisation

**Website**

<http://www.parkerinst.dk>

**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

**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?
<a href="#">Results article</a>	results	01/09/2006		Yes	No