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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

Registration date
19/07/2005

Last Edited
05/11/2008

Recruitment status
No longer recruiting

Overall study status
Completed

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
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 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)

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?
Results article	results	01/09/2006		Yes	No