ISRCTN17726268 https://doi.org/10.1186/ISRCTN17726268

The efficacy and safety of intra-articular injections with the tumour-necrotising factor alpha (TNFa) antagonist infliximab in patients with chronic or recurrent arthritis of the knee

Submission date
19/12/2005

Recruitment status
No longer recruiting

Registration date
19/12/2005

Overall study status
Completed

Last Edited
07/01/2021

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

Contact name
Dr A E van der Bijl

Contact details
Leiden University Medical Centre
Department of Rheumatology
P.O. Box 9600
Leiden
Netherlands
2300 RC
+31 (0)71 5263598
a.e.van_der_bijl@lumc.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
P04-139

Study information

Scientific Title
The efficacy and safety of intra-articular injections with the tumour-necrotising factor alpha (TNFa) antagonist infliximab in patients with chronic or recurrent arthritis of the knee

Study objectives
The systemic treatment of rheumatoid arthritis with anti-tumour necrotising factor alpha (anti-TNFa) is very successful. In a number of case reports varying success rates of intra-articular injections with the TNFa blocking agent infliximab have been reported. In this study we want to assess the safety and efficacy of intra-articular injections with infliximab in patients with relapsing or persistent (mono-) arthritis of the knee.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from the local medical ethics committee

Study design
Randomised double blinded, active controlled parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Arthritis, spondyloarthropathy, rheumatoid arthritis

Interventions
Treatment with infliximab 100 mg intra-articular or methylprednisolone 80 mg intra-articular.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Infliximab

Primary outcome measure
Recurrence or persistence of knee arthritis as defined by either:
1. The need for local therapy such as joint aspiration or injection, arthroscopy or (radio-) synovectomy
2. Non-improvement of knee joint score

Secondary outcome measures
Clinical parameters:
1. The occurrence of (systemic) side effects
2. Physician's assessment of local disease activity as measured by joint swelling as well as pain
3. Patient's functional status measured by a Health Assessment Questionnaire (HAQ)
4. Patient's Visual Analogue Scales (VAS) for local and general pain and overall disease activity
5. Physician's assessment of overall disease activity (VAS)
6. Disease Activity Score (DAS28)
7. Morning stiffness
8. A five-point global assessment scale measuring improvement or deterioration compared to baseline and the previous assessment

Laboratory parameters:
Erythrocyte sedimentation rate (ESR), C-reactive protein (CRP), and immunoglobulin M (IgM) rheumatoid factor titre

Radiological parameters:
Magnetic Resonance Imaging (MRI) quantification of the synovial tissue volume (blinded and at random order)

Overall study start date
16/09/2004

Completion date
30/09/2006

Eligibility

Key inclusion criteria
1. Inflammatory arthritis involving a knee (rheumatoid arthritis, juvenile chronic arthritis, spondylarthropathies and arthritis of unknown origin)
2. Aged above 18 years
3. Written informed consent
4. At least two therapeutic corticosteroid injections in the affected joint within a period of one year

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Haemorrhagic disease
2. Arthritis due to infection, gout or osteoarthritis
3. Participation in any other study which interferes with or is influenced by this study
4. Use of oral prednisone in excess of 10 mg/day
5. Recent change of disease modifying anti-inflammatory drug (DMARD) therapy (six weeks or less)
6. Intra-articular injection with corticosteroid less than two months ago (concerning all joints)
7. Hypersensitivity to methylprednisolone/triamcinolone, lidocain or infliximab (murine proteins) or intravenous (iv) contrast
8. Active/latent tuberculosis
9. Acute/chronic infection
10. Multiple sclerosis
11. Decompensation cordis (New York Heart Association [NYHA] classification III and IV)
12. Pregnancy or lactating females
13. Malignancy
14. Claustrophobia
15. Pacemaker in situ/metal prostheses and/or vascular clips

Date of first enrolment
16/09/2004

Date of final enrolment
30/09/2006

Locations

Countries of recruitment
Netherlands

Study participating centre
Leiden University Medical Centre
Leiden
Netherlands
2300 RC

Sponsor information

Organisation
Leiden University Medical Centre (LUMC) (The Netherlands)

Sponsor details
Department of Rheumatology
PO Box 9600 RC
Leiden
Netherlands
2300 RC

Sponsor type
Hospital/treatment centre

Website
http://www.lumc.nl/english/start_english.html

ROR
https://ror.org/027bh9e22

Funder(s)

Funder type
Not defined

Funder Name
Not provided at time of registration

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	15/07/2009	07/01/2021	Yes	No