

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	<input type="checkbox"/> Prospectively registered
Registration date 19/12/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 07/01/2021	Condition category 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

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

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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)

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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)

ROR

<https://ror.org/027bh9e22>

Funder(s)

Funder type

Not defined

Funder Name

Not provided at time of registration

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