

The Orthokin® trial: a prospective double blind placebo-controlled randomised trial to investigate the effectiveness of autologous interleukin-1 receptor antagonist in the treatment of osteoarthritis (OA)

Submission date 20/12/2005	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 20/12/2005	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 18/11/2008	Condition category Musculoskeletal Diseases	☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

NTR202

Study information

Scientific Title

Study objectives

1. Orthokin® relieves symptoms of pain and dysfunction of OA as determined by the outcome of designated subjective scoring systems
2. Orthokin® reduces inflammatory markers in synovial fluid
3. Orthokin® inhibits long-term radiological progression of OA development

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from the local medical ethics committee

Primary study design

Interventional

Study design

Multicentre, randomised, double-blind, placebo controlled, parallel group trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Arthritis, osteoarthritis

Interventions

The treatment for the patients in both groups will be identical to ensure that both the patient and the treating surgeon are blinded for the treatment the patient received. The treatment comprises a venapuncture to obtain 50 milliliters of blood using the Orthokin® syringe containing the surface treated glass particles. This blood send to the Orthogen laboratory where it is prepared for intra-articular injection. The patients will receive 6 intra-articular injections over a period of 4 weeks, either with Orthokin® or with a placebo. Before administration of the treatment, the synovial fluid present in the treated joints will be collected to prevent dilution of the drug and for measurement of the concentrations of various inflammatory cytokines by multiplex ELISA (Biorad®). Before and 3, 6, 9 and 12 months after the initiation of the treatment, the patients will be asked to fill out a questionnaire (containing a VAS for pain, the Knee injury and Osteoarthritis Outcome Scale (KOOS) and the 100-point knee society clinical rating scale) to evaluate the effectiveness of the treatment. At these time-points the patients will also be asked to return to the outpatient clinic for objective evaluation of the effectiveness of the treatment by their treating surgeon. 12 months after initiation of the treatment is the primary endpoint of this study as the effectiveness of the treatment with respect to the symptomatology of OA will than be evaluated.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Orthokin®

Primary outcome(s)

Questionnaires

Key secondary outcome(s)

X-rays

Completion date

01/09/2006

Eligibility

Key inclusion criteria

1. Typical symptoms for osteoarthritis as judged by the physician
2. Previous treatment more than 6 months ago
3. Patient signed informed consent
4. Patient greater than 18 years old
5. Minimal 40 mm Visual Analogue Scale (VAS) pain
6. Maximal 60 points Knee Society Rating Scale
7. Maximal 60 points KOOS index

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Participation in concurrent trials
2. Participation in previous trials within 3 months
3. Patient know to have human immunodeficiency virus (HIV), hepatitis, cytomegalovirus (CMV) and syphilis infections
4. Alcohol and drug abuse
5. Poor general health condition as judged by the treating physician
6. Received hyaluronic acid and/or corticosteroid intra-articular injections into the afflicted knee within the last 6 months of baseline

7. Intake of specific drugs, such as chondroitin sulfate, diacerein, n-glucosamine, piacledine, capsain within 2 weeks of the baseline visit
8. Any concomitant painful or disabling disease of the spine, the hips or lower limbs that would interfere with evaluation of the afflicted knee
9. Ipsilateral coxarthrosis and hip prosthesis loosening
10. Any clinically significant or symptomatic vascular or neurological disorder of the lower extremities
11. All crystalline, inflammatory and infectious arthropathies
12. Current diagnosis of osteomyelitis
13. OA grade IV
14. Known immunodeficiency
15. Corticosteroid usage
16. Anti-coagulant usage and coagulopathy
17. Morbid obesity

Date of first enrolment

27/01/2004

Date of final enrolment

01/09/2006

Locations

Countries of recruitment

Netherlands

Study participating centre

University Medical Centre Utrecht

Utrecht

Netherlands

3508 GA

Sponsor information

Organisation

University Medical Centre Utrecht (UMCU) (Netherlands)

ROR

<https://ror.org/04pp8hn57>

Funder(s)

Funder type

Industry

Funder Name

Somas Chirurgische Techniek BV (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration