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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

Registration date
20/12/2005

Last Edited
18/11/2008

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

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
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

Study design
Multicentre, randomised, double-blind, placebo 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, 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 venapunction 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 measure
Questionnaires

Secondary outcome measures
X-rays

Overall study start date
27/01/2004

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
182

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 coxarhrosis and hip prothesis 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)

Sponsor details
PO Box 85500
Utrecht
Netherlands
3508 GA

Sponsor type
University/education

Website
http://www.umcutrecht.nl/zorg/

ROR
https://ror.org/04pp8hn57

Funder(s)

Funder type
Industry

Funder Name
Somas Chirurgische Techniek BV (The Netherlands)

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