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Autologous conditioned serum (Orthokine®) compared with hyaluronic acid and placebo injections for the treatment of osteoarthritis. A prospective, randomized, placebo-controlled, double-blind, parallel-design, multicenter trial.

Submission date
13/09/2005

Recruitment status
No longer recruiting

Registration date
19/10/2005

Overall study status
Completed

Last Edited
21/03/2012

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
1

Study information

Scientific Title

Acronym
Orthokine Osteoarthritis Trial

Study objectives
We tested the hypothesis that there are no significant differences between intra-articular injections with either autologous conditioned serum (ACS), hyaluronic acid (HA) and placebo in terms of pain relief or improvement in function or life quality, as determined by validated scoring systems.

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
Multi-centre

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Osteoarthitis of the knee.

Interventions
To compare the efficiacy and safety of intra-articular injections of ACS (Orthokine®), HA (Hya-Ject®) and placebo (saline) in patients with unilateral knee osteoarthritis.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Autologous conditioned serum (Orthokine®), hyaluronic acid

Primary outcome measure
The primary efficacy parameters were the mean changes from baseline in the global Western Ontario MacMaster (WOMAC) score, weight-bearing pain using a visual analogue pain scale (VAS) and global patient assessment (GPA) at weeks 13 and 26.

Secondary outcome measures
Secondary endpoints were the success of therapies measured according to the changes in the different health-related quality-of-life profiles in the SF-8 with regard to baseline scores during the 26 weeks, the changes in the global patient assessment after 7 and 13 weeks and changes on the WOMAC score and the VAS pain score after 7 weeks. In addition the number of adverse events and serious adverse events was used to compare the safety profile of the three treatments groups.

Overall study start date
01/10/2003

Completion date
01/10/2005

Eligibility

Key inclusion criteria
1. Age: over 30 years old
2. Chronic knee pain for at least 3 months measured according to American College of Rheumatology (ACR) criteria (Altman, Asch, et al. 1986)
3. X-ray signs of uni- or bi-lateral osteoarthritis of the knee joint (Kellgren 2 or 3; Ravaud & Dougados 1997)
4. Signed written informed consent
5. At least pain grade 5 (measured on a visual analogue pain scale 0-10)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
400

Key exclusion criteria

Pathologies:
1. Systemic disease of the musculoskeletal system
2. Bone cancer, metastasis or tumor-like lesions in the immediate proximity to the treated joint
3. Fracture in the last 3 months
4. Acute bacterial infection of the knee to be treated
5. Conditions, internal or oncological, which impair the patients general fitness (performance status [PS] >2; New York Heart Association [NYHA] >II)
6. Blood clotting disorders
7. Osteonecrosis of the knee to be treated

Treatment:
1. Treatment of the affected knee due to osteoarthritis with one of the three study medications in the last 6 months
2. Present psychiatric disease requiring therapy
3. Ongoing corticoid therapy

Other:
1. Operation on the affected knee within the last 3 months
2. Pregnant or breast-feeding patients
3. Drug dependency (alcohol, analgesics, opiates, etc.)
4. Lack of mental ability to understand the study procedures due to lack of optimal communication capacity (knowledge of the language, dementia, lack of time)

Date of first enrolment
01/10/2003

Date of final enrolment
01/10/2005

Locations

Countries of recruitment
Germany

Study participating centre
Koenigsallee 53-55
Duesseldorf
Germany
40212

Sponsor information

Organisation
Orthogen (Germany)

Sponsor details

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Sponsor type
Industry

Website
http://www.orthogen.com

ROR
https://ror.org/01qwfvp91

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Department of Orthopedics, University Hospital Düsseldorf

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		01/06/2003		Yes	No
Results article	results	01/10/2003		Yes	No
Results article	results	01/02/2009		Yes	No