

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 19/10/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 21/03/2012	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr Axel WA Baltzer

Contact details
Koenigsallee 53-55
Duesseldorf
Germany
40212
+49 (0)211 828 93710
axel.baltzer@gmx.de

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

Osteoarthritis of the knee.

Interventions

To compare the efficiency 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

Graf Adolf Strasse 43
Duesseldorf
Germany
40210
+49 (0)211 387 0074
carsten.moser@orthogen.com

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