

Efficacy and safety of autologous conditioned serum (ACS/Orthokine®) compared with Triamcinolone in the treatment of symptomatic hip osteoarthritis.

Submission date 07/02/2010	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 08/03/2010	Overall study status Completed	☐ Protocol
Last Edited 08/03/2010	Condition category Musculoskeletal Diseases	☐ 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

Contact name

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Additional identifiers

Protocol serial number

Version 1004

Study information

Scientific Title

Efficacy and safety of autologous conditioned serum (ACS/Orthokine®) compared with Triamcinolone in the treatment of symptomatic hip osteoarthritis. A double-blinded, randomised, controlled, parallel group trial.

Acronym

OrthoCox

Study objectives

There are significant differences between intra-articular injections with either autologous conditioned serum (ACS) and Triamcinoone in terms of pain relief or improvement in function or life quality, as determined by validated scoring systems.

Further reading:

1. Meijer H, Reinecke J, Becker C, Tholen G, Wehling P. The production of anti-inflammatory cytokines in whole blood by physico-chemical induction. *Inflamm Res*. 2003;52(10):404-407. <http://www.ncbi.nlm.nih.gov/pubmed/14520515>
2. Wehling P, Moser C, Frisbie DD, McIlwraith CW, Kawcak CE, Krauspe R, Reinecke J. Autologous Conditioned Serum in the treatment of Orthopaedic diseases - The Orthokine Therapy. *Biodrugs*. 2007;21(5):223-232. <http://www.ncbi.nlm.nih.gov/pubmed/17896838>
3. Baltzer AW, Moser C, Jansen SA, Krauspe R. Autologous conditioned serum (Orthokine) is an effective treatment for knee osteoarthritis. *Osteoarthritis Cartilage*. 2009;17(2):152-160. <http://www.ncbi.nlm.nih.gov/pubmed/18674932>

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Prospective 2 arm double blind (masked observer) randomised controlled parallel group trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Osteoarthritis of the hip

Interventions

Study of ultrasound-guided intra-articular injection regimens in the treatment of symptomatic hip osteoarthritis.

Treatment with ACS / Orhtokin® will be given 3 times as a 2ml intraarticular injection. Since it is an individual mixture, there is no set concentration of anti-inflammatory cytokines.

Triamcinolon (10mg) will be injected once. For the second and third visit the Triamcinolon Group will receive intraarticular injections with saline.

The follow ups will be at the end of the last visit, after 3 months and after 6 months.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Autologous conditioned serum (ACS/Orthokine®)

Primary outcome(s)

1. Mean changes from baseline in the global Western Ontario MacMaster Universities Osteoarthritis Index (WOMAC) score

2. Changes in weight-bearing pain using a numeric rating scale (NRS)

All questionnaires will be filled out as a baseline score before the visit, right after the last of three injections, after 3 months and after 6 months.

Key secondary outcome(s)

1. Success of therapies measured according to the changes from baseline in the different health-related quality-of-life profiles

1.1. SF-12

1.2. Harris Hip Score

1.3. EuroCol-5d

2. The number of adverse events and serious adverse events will be used to compare the safety profile of the two treatments groups.

All questionnaires will be filled out as a baseline score before the visit, right after the last of three injections, after 3 months and after 6 months.

Completion date

31/12/2011

Eligibility**Key inclusion criteria**

1. Age: over 30 years old

2. Chronic hip osteoarthritic (OA) 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 hip joint (Kellgren 2 or 3; Ravaud & Dougados 1997)

4. Signed written informed consent

5. At least pain grade 4 (measured on a numeric rating scale 0-10)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Pathologies:

- 1.1. Systemic disease of the musculoskeletal system
- 1.2. Bone cancer, metastasis or tumour-like lesions in the immediate proximity to the treated joint
- 1.3. Fracture in the last 3 months
- 1.4. Acute bacterial infection of the hip to be treated
- 1.5. Conditions, internal or oncological, which impair the patients general fitness (performance status [PS] >2; New York Heart Association [NYHA] >II)
- 1.6. Blood clotting disorders
- 1.7. Osteonecrosis of the hip to be treated

2. Treatment:

- 2.1. Treatment of the affected hip due to osteoarthritis with one of the two study medications in the last 6 months
- 2.2. Present psychiatric disease requiring therapy
- 2.3. Ongoing corticoid or non-steroidal anti-inflammatory drug (NSAID) therapy due to other diseases

3. Other:

- 3.1. Operation on the affected hip within the last 3 months
- 3.2. Pregnant or breast-feeding patients
- 3.3. Drug dependency (alcohol, analgesics, opiates, etc.)
- 3.4. 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

01/03/2010

Date of final enrolment

31/12/2011

Locations

Countries of recruitment

Germany

Study participating centre

Universitaetstrasse 142

Bochum

Germany

44799

Sponsor information

Organisation

Orthogen AG (Germany)

ROR

<https://ror.org/01qwfvp91>

Funder(s)**Funder type**

Industry

Funder Name

Orthogen AG (Germany)

Funder Name

Clinic and practice for Orthopaedics, Dr. med. Klaus-Dietrich von Bergen (Germany)

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration