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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 [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 08/03/2010	**Overall study status** Completed	
Last Edited 08/03/2010	**Condition category** Musculoskeletal Diseases	

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

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.giv/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.giv/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.giv/pubmed/18674932

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

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

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
A patient information sheet (PIS) in web format will be available shortly. Until then please use contact details below to request a PIS.

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 measure
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.

Secondary outcome measures
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 wil 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.

Overall study start date
01/03/2010

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

Age group
Adult

Sex
Both

Target number of participants
130

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
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Germany
44799

Sponsor information

Organisation
Orthogen AG (Germany)

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Sponsor type
Industry

Website
http://www.orthogen.com

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

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