Different stimulatory properties of blood of osteoarthritic and healthy patients

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The goal of this study is to analyse differences in monocyt activity, by analysis of cytokine levels in serum of healthy and OA patients.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Tendon, ligament and cartilage disorders
Study type	Observational invasive

Summary

ID

NL-OMON32911

Source
ToetsingOnline

Brief title
Arthrotic versus healthy serum

Condition

- Tendon, ligament and cartilage disorders

Synonym
joint degeneration, osteoarthritis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W,Smith & Nephew gelden.

Intervention

Keyword: cytokine, osteoarthritis, serum

Outcome measures

Primary outcome

Differences in cytokine profiles between OA and healthy individuals of the

following cytokines: (IL-1β, IL-4, IL-6, IL-10, IL-13, TNF-α, IFNγ, OSM, OPG,

IL-1RA, TGF-β, IGF-1).

Secondary outcome

Not applicable

Study description

Background summary

Osteoarthritis (OA) is an invaliditating disorder, which can result in pain, a decrease in mobility and inactivity. The underlying cause is degeneration of the joint, leading to a decrease in the load-bearing capacity of the cartilage (Cunningham, Am J Public Health 1984).
Although OA is usually considered as a local, age-related disorder, recent observations demonstrate that systemical processes may play a part in disease progression, which can lead to a change in composition of the blood (unpublished data, Orthopaedics department of the UMCU). These recent observations demonstrate that the cytokine level in blood of healthy patients is different than that of OA patients. An altered monocyt activity may lie at the foundations of this process.
One of the treatment strategies in OA is to interfere with intra-articualr cytokine levels (Auw Yang, OA&C 2008). However, intereference with systemically circulating proteins would possibly be even more effective. In order to develop systemical therapies for treatment of OA, it is necessary to gain knowledhe on cytokine profiles in serum of patients with OA. The discovery of altered cytokine profiles, and thus of an altered monocyt activity, would possibly lead to the development of therapies that interfere with OA in a systemical fashion.

Study objective

The goal of this study is to analyse differences in monocyt activity, by

analysis of cytokine levels in serum of healthy and OA patients.

Study design

In 20 healthy and 20 OA patients, 40 ml of blood will be acquired through venapunction, followed by analysis of cytokineprofiles (IL-1β, IL-4, IL-6, IL-10, IL-13, TNF-α, IFNγ, OSM, OPG, IL-1RA, TGF-β, IGF-1) by ELISA and by Multiplex ELISA.

Study burden and risks

Burden: venapunction (once) which will take approximately 10 minutes
Risk: dizziness or fainting, haemorrhage on the place of injection

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- age higher than 18 years
- signed informed consent
- healthy: no diseases of musculoskeletal system
- OA: patients with OA, as diagnosed by an orthopaedic surgeon

Exclusion criteria

- prior joint replacement

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-03-2009
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	02-12-2008
Application type:	First submission

Review commission: METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL25097.041.08