# FUNCTIONAL GENOMIC RESEARCH IN OSTEOARTHRITIC CARTILAGE

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Joint disorders
Study type	Observational non invasive

# Summary

#### ID

NL-OMON56915

**Source** ToetsingOnline

**Brief title** De \*Research osteoArthritic Articulair Cartilage\* (RAAK) study

# Condition

• Joint disorders

**Synonym** cartilage degeneration, osteoarthritis

**Research involving** Human

### **Sponsors and support**

Primary sponsor: Moleculaire Epidemiologie Source(s) of monetary or material Support: Ministerie van OC&W,Europese unie

### Intervention

Keyword: blood, cartilage, genomic, osteoarthritis

#### **Outcome measures**

#### **Primary outcome**

In order to assess functional effects of OA susceptibility genes in the

relavant disesed tissue in comparison to blood by:

Monitoring of RNA expression profiles in diseased tissue and blood.

Differential allelic expression of susceptibility alleles in diseased tissue

and blood

#### Secondary outcome

Increased knowledge on the OA etiology will allow, in the future, new drugable

targets, better prevention, prognosis and disease management.

# **Study description**

#### **Background summary**

Osteoarthritis (OA) is a common disabling degenerative disease of the joints. Radiographic osteoarthritis in subject above 70 years is very prevalent (80%) whereas in 2010 around 15% of the Dutch population will be above 65 years. The OA phenotype is heterogeneous. Radiographic OA is characterized by joint space narrowin and changes of the subchondral bone whereas clinically subjects suffer of pain, stiffness and disability. Currently there is no drug available that is able to slow down or stop the disease process. Eventulally, subjects with advanced disease will become eligable for a joint replacement. So increased knowledge on mechanism, prevention and adequate therapies on this degenerative disease is a prerequisite to imporve the disease management. It has been shown by various studies the genetic factors play on important role in the onset of primary OA (without a clear cause). Identification of the genes determing this heritabiliy alows insight in to the etiology of hte onset and the progression of the disease. Recently, at the department of Molecular Epidemiology new OA susceptibility genes involved in the thyroid pathway were identified. The current protocol aims to collect bloed and joint tissue of OA patients that undergo a joint replacement. From the blood and joint tissue we will isolate genomic material (DNA en RNA) to proceed toward fucntional genomic assays of thes genes.

#### **Study objective**

The objective of the RAAK study is to collect bloed and joint tissue (cartilage, ligaments and subchondral bone) of patients that undergo a total joint replacement due to a endstage OA. Genomic material (DNA and RNA) will be isolated from both the blood and joint tisse to investigate functional effects of the newly identified OA susceptibility genes. Increased knowledge on the etiology of OA may eventually lead to the discovery of new drugable targets.

#### Study design

From patients that will undergo a joint replacement we will collect blood (1 EDTA tube (8ml) and 1 PAX gene tube (3 ml) and joint tissue during the operation. The joint tissue will consist of the rest material that will come available during the replacement. Bloed and tissue will be stored at the Dept. of Molecular Epidemiology, LUMC. The genomic material will be isolated in time. Long term storage of DNA and RNA and the research will occur at the department of Molecular Epidemiologie.

#### Study burden and risks

There will very little burden and risk for participants of the study. In addition there will be little short term, individual benefit.

# Contacts

**Public** Selecteer

Einthovenweg 20 2333 ZC Leiden NL **Scientific** Selecteer

Einthovenweg 20 2333 ZC Leiden NL

# **Trial sites**

# **Listed location countries**

Netherlands

# **Eligibility criteria**

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

### **Inclusion criteria**

- Patients above 40 years of age that are eligable for a total knee or hip replacement.

- Joint replacements is due to end stage osteoarthritis

# **Exclusion criteria**

-Patients that are obtaining a total knee or hip replacement due to other causes then osteoarthritis

# Study design

### Design

Study type: Observational non invasive	
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	20-02-2009

Enrollment:	
Туре:	

400 Actual

# **Ethics review**

Approved WMO	
Date:	16-02-2009
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

# **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** CCMO

ID NL26083.058.08