

# Cross-sectional study of the characteristics of arthropathy in long-term well-controlled acromegalic patients

Published: 15-11-2006

Last updated: 20-05-2024

The following research questions will be addressed: 1.Is there irreversible joint damage after previous GH excess in long-term cured acromegalic patients?2.What are the clinical characteristics of reported joint problems on clinical examination? 3....

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Hypothalamus and pituitary gland disorders
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON30077

### Source

ToetsingOnline

### Brief title

Arthropathy in acromegaly

### Condition

- Hypothalamus and pituitary gland disorders
- Joint disorders

### Synonym

joint problems in acromegaly (acromegalia)

### Research involving

Human



## Sponsors and support

**Primary sponsor:** Leids Universitair Medisch Centrum

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Acromegaly, Arthropathy, Genetics, Well-controlled

## Outcome measures

### Primary outcome

- clinical parameters: extensive physical examination
- radiological parameters: knee, hands, hip and axial skeleton
- functional parameters: assessment of hand/ shoulder/ lower extremity function
- biochemical parameters: parameters of hormonal status/ inflammation/ osteoarthritis
- DNA: genes associated with predisposition of osteoarthritis and pituitary adenomas

### Secondary outcome

N.A.

## Study description

### Background summary

Despite long-term cure of acromegaly, patients have decreased quality of life scores and a high prevalence of co-morbidity, especially arthropathy and hypertension. Joint problems were reported in 77% of the patients with long-term cured acromegaly. However, the characteristics of these joint problems in cured acromegaly have never been studied.

### Study objective

The following research questions will be addressed:



1. Is there irreversible joint damage after previous GH excess in long-term cured acromegalic patients?
2. What are the clinical characteristics of reported joint problems on clinical examination?
3. What are the radiological characteristics of the reported joint problems?
4. What are the functional implications of the reported joint problems?
5. What are the biochemical characteristics of the reported joint problems?
6. How do the prevalence and characteristics of osteoarthritis in cured acromegalic patients compare to the characteristics in an osteoarthritis cohort?
7. Can we identify genes associated with osteoarthritis and relate this to the extent of joint damage in patients with acromegaly?
8. What is the prevalence of genes increasing the predisposition for pituitary adenomas in patients with acromegaly?

## **Study design**

The study is designed as a cross-sectional observation study in acromegalic patients with long-term control of GH excess.

## **Study burden and risks**

There are no known long-term consequences of methods applied in this research project.

## **Contacts**

### **Public**

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## **Trial sites**



## Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

- Informed consent.
- All patients treated for acromegaly by surgery, radiotherapy and medical treatment and followed at the Dept of Endocrinology with control of disease activity defined as a normal IGF-I for age and/ or a normal glucose-induced GH suppression.
- Appropriate hormonal substitution of dysfunctional hormonal axes.

### Exclusion criteria

- Pregnancy

## Study design

### Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

**Primary purpose:** Basic science

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	15-10-2007



Enrollment:	200
Type:	Actual

## Ethics review

Approved WMO	
Date:	15-11-2006
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO	
Date:	11-03-2015
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

## 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	NL13469.058.06