

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

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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....

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Hypothalamus and pituitary gland disorders
Study type	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

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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