

Arthropathy in acromegaly: Evaluation of Progression, characteristics of Osteophytes, quality of Life and medical care, Imaging and Structure of cartilage in acromegalic patients 2016 (ACROPOLIS 2016)

Published: 28-11-2016

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We aim to further study the characteristics of joint disease in acromegaly and its progression, in order to improve care for this patient group and to get insight into the pathogenesis of osteophytes and cartilage hypertrophy in acromegaly and in...

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

Summary

ID

NL-OMON42983

Source

ToetsingOnline

Brief title

ACROPOLIS 2016

Condition

- Hypothalamus and pituitary gland disorders
- Joint disorders

Synonym

acromegaly; growth hormone producing benign tumor of the pituitary gland

Research involving

Human

Sponsors and support

Primary sponsor: Endocrinologie

Source(s) of monetary or material Support: projectgelden

Intervention

Keyword: acromegaly, arthropathy, progression, quality of life

Outcome measures

Primary outcome

Clinical parameters of regular care, such as biochemical functional parameters

Questionnaires

Radiological parameters

Genetic analyses

Secondary outcome

NVT

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. In the baseline visit of the ACROPOLIS study we reported that patients with acromegaly frequently have generalized radiological and clinical osteoarthritis. However, the distribution of radiological abnormalities, such as osteophytes and joint space narrowing is different compared with primary osteoarthritis. In our first follow-up visit, 2.5 years after baseline, we reported radiographic progression in over 70% of patients. Subjective progression and clinical complaints deteriorated as well. As previously described, changes in clinical symptoms were not associated with radiographic progression. Moreover, we reported that treatment with SMS

analogues was associated with an increased radiographic osteoarthritis progression.

Study objective

We aim to further study the characteristics of joint disease in acromegaly and its progression, in order to improve care for this patient group and to get insight into the pathogenesis of osteophytes and cartilage hypertrophy in acromegaly and in primary osteoarthritis.

Study design

Cross-sectional longitudinal observational follow-up study

Study burden and risks

NVT

Contacts

Public

Selecteer

Albinusdreef 2
Leiden 2333ZA
NL

Scientific

Selecteer

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Acromegaly

Exclusion criteria

age <18 years or > 70 years old

mentally incompetent

pregnancy

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): 02-12-2016

Enrollment: 100

Type: Actual

Ethics review

Approved WMO

Date:	28-11-2016
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO	
Date:	23-08-2017
Application type:	Amendment
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	ID
CCMO	NL58163.058.16

Study results

Date completed:	15-09-2021
Actual enrolment:	25