# Facial and hand analysis, sleep apnea and speech in patients with acromegaly: a prospective study to investigate changes in craniofacial and hand characteristics, sleep apnea and speech during treatment and after remission.

Published: 24-05-2012
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To investigate the changes in facial- and hand analysis in patients with acromegaly as a result of medical treatment and pituitary surgery, and to investigate the changes in relational proportions between facial- and hand structures, incidence and...

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Endocrine and glandular disorders NEC |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON41364

**Source**
ToetsingOnline

**Brief title**
Prospective study on changes in acromegaly

### Condition

- Endocrine and glandular disorders NEC
- Upper respiratory tract disorders (excl infections)
- Skin and subcutaneous tissue disorders NEC

**Synonym**
Growth hormone excess

**Research involving**
Human

## Sponsors and support

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

## Intervention

**Keyword:** Acromegaly, Craniofacial, Sleep apnea, Speech

## Outcome measures

### Primary outcome

Parameters of facial analysis with 3D stereophotography and cone beam CT and hand analysis with 3D stereophotography respectively, biochemical parameters of disease activity, disease related and general QOL using the AcroQol and RAND-36 questionnaires, speech analysis and the voice handicap index questionnaire and severity of sleep apnea using complete overnight polysomnography and the Epworth sleepiness scale questionnaire.

### Secondary outcome

In vitro inflammatory cytokineproduction and foam cell formation of monocytes obtained from patiënts with acromegaly

# Study description

### Background summary

Acromegaly is the clinical syndrome that results from an excess of growth hormone (GH). Craniofacial and hand disproportions due to soft tissue swelling and new bone formation are highly prevalent in patients with active acromegaly. Besides the cosmetic aspects, these changes can impair the quality of life because of the significant morbidity with respect to oral, maxillofacial and hand pathologies as well as respiratory problems such as sleep apnea and

changes in speech. At present it is unclear if these craniofacial and hand disproportions, sleep apnea and speech changes are (partially) reversible after successful treatment. Therefore there is no consensus about the information patients should be given about (partial) recovery of facial and hand disproportions after treatment and how the follow-up with respect to oral, maxillofacial, respiratory and hand pathology should be organized. Facial and hand analysis using a 3D stereophotograph and a 3D fusion model of a 3D stereophotograph and a 3D skull reconstruction via cone beam computed tomography (CT)-scan makes it possible to investigate the craniofacial changes due to acromegaly in all facial dimensions together (dentition, bone and soft tissue) and the relational proportions between these facial structures. 3D stereophotography can do the same for the soft tissues of the hand. Combined with disease specific and general quality of life (QOL) questionnaires, a correlation between quality of life and craniofacial and hand disproportions can be determined. Combined with sleep- and speech analysis, a correlation between sleep apnea, speech and craniofacial disproportions can be determined.

## Study objective

To investigate the changes in facial- and hand analysis in patients with acromegaly as a result of medical treatment and pituitary surgery, and to investigate the changes in relational proportions between facial- and hand structures, incidence and severity of sleep apnea and incidence and severity of speech changes.

## Study design

Prospective case-control study.

## Study burden and risks

As a result of participating in this study, subjects have to undergo a 3D stereophotograph and a 3D cone beam CT. The cone beam CT is associated with exposure to X-ray radiation of 0.069-0.135mSv. This is the same amount of radiation as the amount of background radiation that each person receives in 7 days time during daily life. No adverse effects are expected from this amount of exposure. The investigation will take 20-40 minutes adjacent to every outpatient clinic visit.
Patients undergo venipuncture as part of their standard care. The additional blood samples required for this study will be obtained during regular outpatient clinic blood dwaring procedures. Patients will not undergo an additional venipuncture. Therefore, this addition to the original protocol is associated with no signifant burden.

# Contacts

**Public**
Selecteer

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**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

- Newly diagnosed acromegaly
- Diagnosis is biochemically confirmed by an increased IGF-1 level (mean +2 standard deviations for age) and insufficient suppression of serum GH levels (e.g. GH levels >= 2mU/l) during oral glucose tolerance test.
- Subjects should be over 18 years old with the ability to read and comprehend the Dutch language

## Exclusion criteria

- Pregnancy
- Maxillofacial surgical treatment in the past.

- Hand surgery in the past
- Speech pathology unrelated to acromegaly

# Study design

## Design

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| 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

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 11-10-2012 |
| Enrollment: | 60 |
| Type: | Actual |

# Ethics review

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| Approved WMO Date: | 24-05-2012 |
| Application type: | First submission |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO Date: | 26-06-2012 |
| Application type: | Amendment |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO Date: | 10-11-2015 |
| Application type: | Amendment |

Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

# 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 | NL39882.091.12 |