

# Evaluation of Intraoperative and early postoperative Growth Hormone Levels for Transsphenoidal Resection in Acromegaly

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Determination of prognostic value of intraoperative growth hormone levels on postoperative curation for acromegaly in patients undergoing transsphenoidal resection of pituitary adenoma.

|                              |  |
|------------------------------|--|
| <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 invasive                     |

## Summary

### ID

NL-OMON41147

### Source

ToetsingOnline

### Brief title

Evaluation of Intra-operative Growth Hormone for Acromegaly

### Condition

- Hypothalamus and pituitary gland disorders
- Nervous system neoplasms benign
- Nervous system, skull and spine therapeutic procedures

### Synonym

acromegaly, growth hormone producing pituitary adenoma

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum

**Source(s) of monetary or material Support:** Bepaling groeihormoon wordt door de afdeling neurochirurgie bekostigd.

## Intervention

**Keyword:** Acromegaly, Growth hormone, Remission, Transsphenoidal surgery

## Outcome measures

### Primary outcome

The acquired growth hormone levels will be compared with the outcome of the OGTT (which is planned according to current protocol) in order to determine cure. Subsequently the predictive value of preoperative growth hormone levels for cure of acromegaly can be determined.

### Secondary outcome

none

## Study description

### Background summary

Acromegaly is characterized by elevated serum levels of growth hormone (GH) and Insulin-like growth factor 1 (IGF-1). In most cases this is due to a growth hormone producing pituitary adenoma. Transsphenoidal resection is the primary treatment option for this condition (7).

In current guidelines the postoperative criteria for remission are considered a nadir GH level on an oral glucose tolerance test (OGTT) of  $\leq 1 \mu\text{g/L}$  ( $1 \mu\text{g/L} = 2.7 \text{ mIU/L}$ ) and a normalized IGF-1 (7). These biochemical criteria have shown to indicate safe levels of GH secretion and absolute remission in substantially all surgical cases (1).

Guidelines currently recommend to perform an OGTT and IGF-1 measurement 12 weeks postoperatively in order to determine remission (7). During this period definite remission is awaited and no additional treatment is started (surgical

re-exploration, medical therapy, radiotherapy).

Determination of remission in direct postoperative phase enables more adequate treatment. Re-exploration, which is the first choice after primary surgery failed to achieve remission, is facilitated in the early postoperative period (first week). Within the same week surgical remission could be attained omitting other additional treatments and unnecessary additional radiological and endocrinological studies.

GH has a short half-life and it has been demonstrated to show rapid intraoperative and postoperative decline (4). This makes it an possible adequate marker for quick postoperative and even intraoperative predictor of remission (4). Although current guidelines recognize correlation of early postoperative GH levels (<2 ug/ml) and long term remission, exact correlation is unknown (7). Intraoperative measurements of GH levels are considered not clinically useful given current literature (7). The few studies evaluating GH levels are all retrospective in design which limits their value for guidelines (2,3,4,5,6).

Our study will be the first to prospectively evaluate early postoperative GH levels in relation to surgical remission. In order to enlarge our subject numbers for current study other Dutch university medical centers are approached for possible future participation. Current assay used for GH in our institution does not support immediate display of results. Our study is needed to determine if such assay is useful to facilitate GH evaluation during surgery.

1. Ronchi CL, Varca V, Giavoli C, Epaminonda P, Beck-Peccoz P, Spada A, Arosio M.

Long-term evaluation of postoperative acromegalic patients in remission with previous and newly proposed criteria. J Clin Endocrinol Metab. 2005 Mar;90(3):1377-82.

2. Kim EH, Oh MC, Lee EJ, Kim SH. Predicting long-term remission by measuring immediate postoperative growth hormone levels and oral glucose tolerance test in acromegaly. Neurosurgery. 2012 May;70(5):1106-13.

3. Abe T, Lüdecke DK. Recent primary transnasal surgical outcomes associated with intraoperative growth hormone measurement in acromegaly. Clin Endocrinol (Oxf). 1999 Jan;50(1):27-35.

4: van den Berg G, van Dulken H, Frölich M, Meinders AE, Roelfsema F. Can intra-operative GH measurement in acromegalic subjects predict completeness of surgery? Clin Endocrinol (Oxf). 1998 Jul;49(1):45-51.

5: Valdemarsson S, Ljunggren S, Cervin A, Svensson C, Isaksson A, Nordström CH, Siesjö P. Evaluation of surgery for acromegaly: role of intraoperative growth hormone measurement? Scand J Clin Lab Invest. 2001;61(6):459-70.

6: Sarkar S, Jacob KS, Pratheesh R, Chacko AG. Transsphenoidal surgery for acromegaly: predicting remission with early postoperative growth hormone assays.

Acta Neurochir (Wien). 2014 Jul;156(7):1379-87;

7: American association of clinical endocrinologists medical guidelines for clinical practice for the diagnosis and treatment of acromegaly \* 2011 update

8: Feelders RA, Bidlingmaier M, Strasburger CJ, Janssen JA, Uitterlinden P, Hofland LJ, Lamberts SW, van der Lely AJ, de Herder WW. Postoperative evaluation

of patients with acromegaly: clinical significance and timing of oral glucose tolerance testing and measurement of (free) insulin-like growth factor I, acid-labile subunit, and growth hormone-binding protein levels. J Clin

Endocrinol

Metab. 2005 Dec;90(12):6480-9

## **Study objective**

Determination of prognostic value of intraoperative growth hormone levels on postoperative cure for acromegaly in patients undergoing transsphenoidal resection of pituitary adenoma.

## **Study design**

prospective

## **Study burden and risks**

Low, additional collecting of blood will be done when patients are under general anesthesia from protocolar placed arterial catheter. Postoperative growth hormone levels will be determined from protocolar collected blood samples.

## **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

Patients with acromegaly and selected for elective transsphenoidal resection pituitary adenoma in the AMC.

### Exclusion criteria

All patients that are selected for elective transsphenoidal pituitary adenoma resection for acromegaly are included. When, after being informed about the research protocol, patients do not wish to participate they will not be included.

## Study design

### Design

**Study type:** Observational invasive

|                  |                         |
|------------------|-------------------------|
| Masking:         | Open (masking not used) |
| Control:         | Uncontrolled            |
| Primary purpose: | Treatment               |

## Recruitment

|                           |                     |
|---------------------------|---------------------|
| NL                        |                     |
| Recruitment status:       | Recruitment stopped |
| Start date (anticipated): | 31-03-2015          |
| Enrollment:               | 30                  |
| Type:                     | Actual              |

## Ethics review

|                    |                    |
|--------------------|--------------------|
| Approved WMO       |                    |
| Date:              | 13-01-2015         |
| Application type:  | First submission   |
| Review commission: | METC Amsterdam UMC |

## 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     | NL50641.018.14 |