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

Published: 13-01-2015
Last updated: 21-04-2024

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

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Hypothalamus and pituitary gland disorders
Study type	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 afeling 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 plannend according to current protocol) in order to determine

curation. Subsequently the predictive value of peroperative growth hormone

levels for curation of acromegaly can be determined.

Secondary outcome

none

Study description

Background summary

Acromegaly is characterized by elevated serum levels of growth hormone (GH) and Insuline 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 *1 ug/l (1 ug/l = 2.7 mE/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 curation 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. Postoperatieve growth hormone levels will be determined from protocolar collected blood samples.

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

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