Growth hormone deficiency in patients in long-term remission of adrenal Cushing's syndrome

Published: 22-02-2011
Last updated: 27-04-2024

To assess the presence of GH deficiency in patients who are in long-term remission of Cushing*s syndrome due to adrenal adenoma.

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

Summary

ID

NL-OMON36195

Source
ToetsingOnline

Brief title
GH deficiency after adrenal Cushing*s syndrome

Condition

- Hypothalamus and pituitary gland disorders

Synonym
groeihormoondeficiëntie

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: De exacte financiering is nog niet rond;maar er wordt onderhandeld met de farmaceutische industrie.,Mogelijk. Hier wordt nog over onderhandeld.

Intervention

Keyword: Cushing□s syndrome, Growth hormone deficiency

Outcome measures

Primary outcome

GH secretory response to an ITT or an Arginine/GHRH test. The endpoint is GH

deficiency as defined in the consensus of the endocrine society in 2006.

Secondary outcome

Not applicable.

Study description

Background summary

Several studies have demonstrated impaired growth hormone (GH) secretion as well as absent or blunted GH response to stimuli in patients with active Cushing*s syndrome. Although the exact pathophysiology of this effect is not fully understood, it has been postulated that prolonged exposure to supraphysiological levels of cortisol is the major cause of this abnormality. Following cure of Cushing*s syndrome and thus resolution of hypercortisolism, recovery of GH secretory status is often seen, but certainly not in all patients. Because most patients with CS have Cushing*s disease caused by a pituitary adenoma it is thought that damage of the pituitary gland by surgery of radiotherapy is the cause of this lasting GH deficiency. However, lasting GH deficiency after treatment of adrenal CS has also been reported in one small study (Tzanela et al 2003). Recently we observed unexpected low insulin growth factor type-1 levels in our patients that have been treated for adrenal CS in the past. We therefore hypothesize that GH deficiency in patients that are in remission of CS may be a remaining effect of the supraphysiological levels of cortisol that they were exposed to for a substantial period.
To examine this hypothesis we plan to assess the GH response to an insulin tolerance test (ITT) or an Arginine/GHRHtest in patients who are in long-term remission of Cushing*s syndrome due to adrenal adenoma. In this group of patients, GH deficiency cannot be explained by pituitary damage due to surgery, radiotherapy or a pituitary adenoma in situ.

Study objective

To assess the presence of GH deficiency in patients who are in long-term remission of Cushing*s syndrome due to adrenal adenoma.

Study design

Observational pilot study in which 16 patients who are in remission of Cushing*s syndrome due to adrenal adenoma will be included.
They will undergo an ITT or an Arginine/GHRH test if there are contra-indications for the first.

Study burden and risks

Following venapuncture a local haematoma can occur. During the ITT hypoglycaemia is induced which may cause the following side-effects; sweating, palpitations, and rarely convulsions and even of loss of consciousness due to severe hypoglycemia. The glucose level in the blood as well as the wellbeing of the patient will be monitored closely. A physician and a nurse will be present during the test. Beside the patient*s bed a vial of glucose 50% will be ready for use. It will be administered intravenously if the patient is showing signs of impaired consciousness.
During the Arginine/GHRH test the administration of the Arginine can cause a warm feeling. Very rarely an anaphylactic reaction can occur. All drugs to treat this reaction will be available in the testingroom. Both the ITT and the Arginine/GHRH test are well validated tests to investigate GH-response and are used frequently in normal clinical practice.
This patientgroup could benefit from undergoing this test. Nowadays there is a treatment for patients with GH deficiency.

Contacts

Public
Universitair Medisch Centrum Sint Radboud

Geert Grooteplein 8
6500HB Nijmegen
NL
Scientific
Universitair Medisch Centrum Sint Radboud

Geert Grooteplein 8
6500HB Nijmegen
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Remission of Cushing*s syndrome due to adrenal adenoma for at least four years.
- Proven remission by a 1 mg dexamethasone suppression test within the last year.

Exclusion criteria

- Patients cured of an adrenal carcinoma.
- BMI >30 kg/m2.

Study design

Design

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

Recruitment status:	Recruiting
Start date (anticipated):	07-03-2011
Enrollment:	16
Type:	Actual

Ethics review

Approved WMO Date:	22-02-2011
Application type:	First submission
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	NL35574.091.11