Effects of growth hormone (GH) replacement therapy in GH deficient adult childhood cancer survivors on organ size and microvascularisation of kidney and skin.

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The primary objective is to study the effects of GH substitution therapy in adult GH deficient survivors of childhood cancer. Primary endpoints are organ size, renal function and capillary density of the skin.

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

Summary

ID

NL-OMON33094

Source
ToetsingOnline

Brief title
Effects of GH replacement therapy on organ size and microvascularisation.

Condition

- Hypothalamus and pituitary gland disorders
- Renal disorders (excl nephropathies)

Synonym
growth hormone deficiency

Research involving
Human

Sponsors and support

Primary sponsor: Novo Nordisk
Source(s) of monetary or material Support: Novo Nordisk

Intervention

Keyword: childhood cancer survivors, growth hormone therapy, microvascularisation, organ size

Outcome measures

Primary outcome

1. Change in visceral organ size, especially kidney size.

2. Change in GFR and ERPF.

3. Change in capillary density of the skin.

Secondary outcome

Change in quality of life.

Study description

Background summary

Survival of children treated for brain tumors has improved dramatically in the last decades. This is a result of improved neurosurgical techniques, radiotherapy and chemotherapy. However, this success is accompanied by some serious late effects of both disease and treatment. One of the late effects of radiotherapy invariably is growth hormone deficiency (GHD). The radiation effects are dose and time dependent. GHD is always seen within 2 years after a radiation dose of > 35 Gy at the pituitary-hypothalamic region. With radiation doses of 27-35 Gy approximately 50% will develop GHD within 2 years. However, the other 50% will develop GHD several years later. At this point adulthood may already been reached.
GHD results during childhood in attenuated growth. When the final height has not been reached, delayed growth is the most important clue to GHD. This clue disappears when GHD becomes apparent only during adolescence or adulthood. GHD also leads to adverse metabolic effects like a reduced peak bone mass and dyslipidemia with central obesity.
It is unknown if and how GH contributes to the development of organs and

microcirculation during normal growth. This is important to know because microcirculation is critical for normal organ function. In view of their age and their life expectancy it is important to optimize normal organ size and function.

Study objective

The primary objective is to study the effects of GH substitution therapy in adult GH deficient survivors of childhood cancer.
Primary endpoints are organ size, renal function and capillary density of the skin.

Study design

50 patients with GHD as a late consequence of radiotherapy for childhood cancer will be asked to participate in this study. Regular care involves growth hormone substitution therapy for these patients. In order to describe the effects of growth hormone therapy, at baseline (before start GH) and after one year of GH treatment visceral organ size (especially kidney size) will be determined by means of CT scan. In addition, renal function (GFR and ERPF) and capillary density of the skin will be measured.

Intervention

1 year of growth hormone substitution therapy.

Study burden and risks

The nature and extent of the burden consists of two one-day visits to the day-care centre for determination of the FGR and ERPF. For this test an i.v. drip with light radioactive fluid will be inserted. To prevend the uptake of the radioactive fluid in the thyroid gland, the patient will drink a mixture of 10 drops of iodine and orange juice. Bloodpressure and pulse will be checked during the examination, 5 times blood will be drawn (80 mL) and the patient has to produce urine on 3 separate occasions during this test. After this test capillary microscopy is performed by looking at the nail under the microscope. This is a non invasive procedure with a duration of approximately 10 minutes. In addition a CT scan is performed of the abdomen. All these tests are incorporated in normal clinical care and no associated side effects are to be expected.
Several questionaires on health, general wellbeing and cognition will be answered.

These tests are repeated after one year of growth hormone substitution therapy.

During the treatment year 2 visits to our outpatient clinic will be scheduled.

In addition, on 5 occasions 10 mL of blood will be drawn. Results be be discussed in another 3 telephone calls.

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

childhood cancer survivors who have been treated with cranial irradiation
growth hormone deficient
age > 18 years
> 5 years off tumor treatment

Exclusion criteria

growth hormone replacement therapy in the last 12 months
current treatment for second malignancy
severe mental disorder/dementia/inability of legal consent
drug abuse/dependence
for women: pregnancy

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2009
Enrollment:	50
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL27406.042.09