Medical assessment of adverse health outcomes in Dutch childhood cancer survivors; a nationwide project; SKION LATER Q2008 onderzoek: Adult growth hormone deficiency in childhood cancer survivors

Published: 23-01-2015
Last updated: 27-04-2024

To assess the diagnostic accuracy of total and free IGF-1 concentrations by comparing it to the gold standard for detection of growth hormone deficiency in adults, i.e. the insulin tolerance test, in subgroups of patients at risk for growth hormone...

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

Summary

ID

NL-OMON47806

Source
ToetsingOnline

Brief title
SKION LATER Q2008 - adult growth hormone deficiency

Condition

- Hypothalamus and pituitary gland disorders

Synonym
growth hormone deficiency in childhood cancer survivors, late pituitary growth hormone deficiency effects of treatment for childhood cancer

Research involving
Human

Sponsors and support

Primary sponsor: Stichting Kinderoncologie Nederland
Source(s) of monetary or material Support: Stichting quality of life gala

Intervention

Keyword: childhood cancer survivors, endocrine deficiency, growth hormone deficiency

Outcome measures

Primary outcome

* Objective 1: free/bioactive, total IGF-1 concentrations, and their age and

gender corrected standard deviation score (SDS-score).

* Objective 2: diagnostic accuracy of free and total IGF-1 concentrations in

the identification of growth hormone deficiency.

Secondary outcome

not applicable

Study description

Background summary

Growth hormone deficiency (GHD) is the most common long term complication of patients who received cranial radiotherapy (RT). The radiation-induced damage to the hypothalamic-pituitary axis is both dose and time dependent and may only become apparent after a latency of many years until in advanced adulthood (1). GHD has several unfavorable effects on health status in children as well as in adults. Children with GHD show attenuated linear growth or blunting of the pubertal growth spurt. GHD in adults is associated with decreased quality of life (2) , fatigue, impaired cognitive functioning, decreased mass of muscle and bone, components of the metabolic syndrome and (most likely) cardiovascular disease. Symptoms of GHD can be reversed by growth hormone substitution therapy (3).
The gold standard for the diagnosis of GHD is the insulin tolerance test, which

is time consuming, inconvenient to the patient and contraindicated in certain instances. In such cases an arginine stimulation test is recommended.
Traditionally, screening for GHD is performed by measurement of IGF-1 and reduced concentrations of IGF-1 levels are highly suggestive of GHD. But a normal IGF-1 does not rule out GHD, especially after cranial irradiation and in patients with characteristics of the metabolic syndrome (4). The latter is very common in childhood cancer survivors, and contributes to the low sensitivity of IGF-1 to detect patients with GHD. Measurement of free/bioactive IGF-1 may circumvent the shortcomings of the (total) IGF-1 assay, but its diagnostic accuracy for this patient group remains to be proven (5).
Identification of patients with GHD is essential because this offers an evidence based treatment option, with among other effects, an improvement in quality of life. This study examines the best diagnostic strategy for the identification of GHD in childhood cancer survivors at risk for development of GHD.

Study objective

To assess the diagnostic accuracy of total and free IGF-1 concentrations by comparing it to the gold standard for detection of growth hormone deficiency in adults, i.e. the insulin tolerance test, in subgroups of patients at risk for growth hormone deficiency and the distribution of total and bioactive IGF-I.

Study design

This study with cross sectional design will consist of an anamnesis and physical exam, for a subpopulation of 160 survivors a ITT, and a venapuncture. for a substantial part of the population, these tests will be part of regular patient follow up as defined by the guidelines for screening for late toxicity in CCS. Data will be collected anonymously in a central database.

Study burden and risks

the largest part of the participants (n=1300) / controles, will get a outpatient visit and venapuncture as part of their regular follow up based on screening guidelines for CCS. The part of the study for the radiotherapy patients (n=160,120 minutes), the outpatient visit and venapuncture is part of the regular follow up based on screening guidelines for CCS.

Contacts

Public
Stichting Kinderoncologie Nederland

Heidelberglaan 25
Utrecht 3584CS
NL
Scientific
Stichting Kinderoncologie Nederland

Heidelberglaan 25
Utrecht 3584CS
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

treated with radiotherapy. Age >= 18 years, >= 5 years off tumor treatment, on stable concomitant medications for 1 month prior to entry of study, otherwise normal pituitary function or on stable hormonal replacement, no treatment for growth hormone deficiency at the time of the tests

Exclusion criteria

pregnancy, active neoplasm, abnormal pituitary functions or recently started concomitant medications

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:	Recruitment stopped
Start date (anticipated):	04-05-2016
Enrollment:	1500
Type:	Actual

Ethics review

Approved WMO Date:	23-01-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-04-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-01-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-06-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-05-2018

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-08-2018
Application type:	Amendment
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	NL34997.018.11