Follow-up study of subjects who participated in the IUGR-1, IUGR-2 and PROGRAM/PREMS study during childhood and early adulthood - Long term effects of growth hormone many years after discontinuation

Published: 18-02-2015
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To evaluate the long-term effects of GH-therapy on metabolic profile and risk factors for cardiovascular diseases in adults (aged 25-35 years) born SGA and compare this with non-treated adults born SGA and with adults born AGA.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON47841

Source
ToetsingOnline

Brief title
Follow-up study of ex-participants of the IUGR-1, 2 and PROGRAM/PREMS study

Condition

- Other condition
- Glucose metabolism disorders (incl diabetes mellitus)
- Sexual function and fertility disorders

Synonym
Short children born small for gestational age

Health condition

cardiovasculaire ziektes

Research involving

Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Novo Nordisk

Intervention

Keyword: Cardiovascular disease, Growth hormone, Insulin sensitivity, Small for gestational age

Outcome measures

Primary outcome

Insulin resistance

Secondary outcome

Blood pressure, body composition, lipid profile, endothelial function and

gonadal function.

Study description

Background summary

Epidemiological studies demonstrated an association between being born Small for Gestational Age (SGA) and an increased risk of adult diseases such as essential hypertension, non-insulin dependent diabetes mellitus and ischaemic heart disease at a relatively young age. Subjects born SGA without spontaneous catch-up growth, are nowadays treated with Growth Hormone (GH) to increase adult height. GH has positive effects on the metabolic profile and cardiovascular risk factors on the short-term, but long-term effects are less known. Changes in the metabolic profile and development of cardiovascular diseases develop over a long period of time. It is therefore important to perform a long-term follow-up on previously GH-treated subjects born SGA, to assess the long-term effects of GH treatment on metabolic profile and

cardiovascular risk factors, compared to non-GH-treated subjects born SGA and compared to non-GH treated subjects born Appropriate for Gestational Age (AGA).

Study objective

To evaluate the long-term effects of GH-therapy on metabolic profile and risk factors for cardiovascular diseases in adults (aged 25-35 years) born SGA and compare this with non-treated adults born SGA and with adults born AGA.

Study design

Observational study comprising one day visit to the Erasmus MC Hospital, Rotterdam.

Study burden and risks

During one day visit, various tests will be performed, including a general physical examination, anthropometric measurements, a DEXA-scan, a Frequently Sampled Intravenous Glucose Tolerance (FSIGT) test, blood pressure measurement, an ultrasound of the carotid arteries and abdomen, an MRI cerebrum and abdomen and a WAIS intelligence test. Prior to the visit, participants will be asked to fill out questionnaires about quality of life and socio-economic status.
From our experience with follow-up studies with similar tests, participants do not experience these tests as a burden. The only invasive test is the FSIGT because it comprises the insertion of two intravenous lines, one for glucose infusion and one for blood sampling. The DEXA-scan has a very low radiation dose and takes only 10 minutes. The ultrasounds of the carotid arteries and abdomen are non-invasive. In case of claustrophobia we will discuss with the participant if the MRI can take place.

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

Former participant of the IUGR-1, IUGR-2 or PROGRAM/PREMS study

Exclusion criteria

Duration of growth hormone treatment less than 4 years

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated):	18-05-2015
Enrollment:	400
Type:	Actual

Ethics review

Approved WMO Date:	18-02-2015
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	18-02-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	17-05-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	11-12-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL50437.078.14