Brain development after prenatal growth retardation; effects of growth hormone treatment.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29167

Source
Nationaal Trial Register

Brief title
sga brain development study

Health condition

Study populations:
group A/B: small for gestational age (sga), children without complete catch up growth with and without growth hormone treatment
group C: sga with complete catch up growth
group D:. Children born with a normal birth weight/length and a normal postnatal growth.

Sponsors and support

Primary sponsor: Prof Dr HA Delemarre- van de Waal

Intervention

Outcome measures

Primary outcome

1. To determine the effect of prenatal growth retardation on brain functioning / development;
2. to determine the effect of growth hormone treatment on brain functioning / development in children born after prenatal growth retardation;
3. to assess wether there is a difference in brain development in between sga children with and without postnatal catch up growth.

Secondary outcome

N/A

Study description

Background summary

This study aims to evaluate the effect of growth hormone treatment on brainfunctioning/ development in children born after prenatal growth retardation. Whether cognitive functions in children born with a low birth weight are impaired due to inappropriate developmental outgrowth is unknown. This is also the case for the fact whether GH treatment from the age of 4 years is still capable to stimulate neuronal outgrowth. We expect the presented study design in which functional imaging techniques and neuropsychological assessment are combined, to increase understanding on the impact of GH therapy on higher brain functioning in children with SGA.

Study objective

This study aims to evaluate the effect of growth hormone treatment on brain functioning and development in children born with a low birth weight/length with incomplete catch up growth.
The two other hypotheses this study aims to evaluate are
a. Is there a difference in brain functioning in children born with a low birth weight/length between those without and with complete catch up growth?
b.Will intra-uterine growth failure affect brain development/functioning?

Intervention

Structural (only at baseline) and functional MRI’s, MEG and extensive neuropsychologic testing will be performed at baseline, after one year and three years in both groups A (treatment with growth hormone (somatropin) and B (without treatment).
SGA patients older than 6 years of age, with incomplete catch-up growth with the indication of GH treatment, will be followed on neuropsychologic functioning.

hypothesis 2/ 3:
In groups C and D structural and functional MRI’s, MEG and extensive neuropsychological testing will be performed only at start of the study.

Contacts

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Eligibility criteria

Inclusion criteria

Inclusion criteria group A/B:
1.Birth weight or birth length below –2 SD adjusted for duration of pregnancy;
2. Present height below –2.5 SD and at least 1 SD below target height-SDS;
3. Calendar age between 4 and 6 years.
4. No evidence of catch up growth during the preceding year;
5. Children are under regular control by pediatrician, choose to be or not to be treated with GH.
Inclusion criteria group C:
1. Birth weight or birth length below –2 SD adjusted for duration of pregnancy;
2. Present height above -2.0 SD and above minus 1 SD of target height -SDS.
Inclusion criteria group D:
1. Normal birth weight/length adjusted for duration of pregnancy;
2. Present height above –2 SD for age and within target range (TH ± 1SD).

Exclusion criteria

1. Known syndromes and serious dysmorphic symptoms suggestive for a syndrome that has not yet been described, except for Silver Russell Syndrome;
2. Severe asphyxia (defined as Apgar score <3 after 5 minutes), and no serious diseases such as long-term artificial ventilation and oxygen supply, bronchopulmonary dysplasia or other chronic lung disease;
3. Coeliac disease and other chronic or serious diseases of the gastrointestinal tract, heart, genito-urinary tract, liver, lungs, skeleton or central nervous system, or chronic or recurrent major infectious diseases, nutritional and/or vitamin deficiencies;
4. Any endocrine or metabolic disorder such as diabetes mellitus, diabetes insipidus, hypothyroidism, or inborn errors of metabolism, except of GHD;
5. Medications or interventions during the previous 6 months that might have interfered with growth, such as corticosteroids (including high dose of corticosteroid inhalation), sex steroids, growth hormone, or major surgery (particularly of the spine or extremities);
6. Use of medication that might interfere with growth during GH therapy, such as corticosteroids, sex steroids, LHRH analogue;
7. Active or treated malignancy or increased risk of leukemia;
8. Serious suspicion of psychosocial dwarfism (emotional deprivation);
9. Severe neurological disability;
10. Expected non-compliance;
11. Prematurity < 35 weeks;
12. For MEG/MRI investigation: Treatment with irremovable metal wires.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2007
Enrollment:	110
Type:	Anticipated

Ethics review

Not applicable
Application type: Not applicable

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
NTR-new	NL851
NTR-old	NTR865
Other	: N/A
ISRCTN	ISRCTN20279720

Study results

Summary results
N/A