

Brain Development after prenatal growth retardation: effects of growth hormone treatment

Submission date 26/02/2007	Recruitment status No longer recruiting	☒ Prospectively registered
Registration date 26/02/2007	Overall study status Completed	☐ Protocol
Last Edited 26/08/2021	Condition category Nutritional, Metabolic, Endocrine	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
NL851 (NTR865)

Study information

Scientific Title
Brain Development after prenatal growth retardation: effects of growth hormone treatment

Acronym

SGA Brain Development study

Study objectives

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:

1. 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?
2. Will intra-uterine growth failure affect brain development/functioning?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval received from the Medical Ethics Review Committee of de Vrije Universiteit medical centre, Amsterdam on the 1st March 2007 (ref: 06/279).

Primary study design

Interventional

Study design

Non-randomised parallel group trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Small for Gestational Age (SGA), brain development

Interventions

Structural (only at baseline) and functional MRIs, 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 six 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 MRIs, MEG and extensive neuropsychological testing will be performed only at start of the study.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

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 whether there is a difference in brain development in between SGA children with and without postnatal catch up growth

Key secondary outcome(s)

No secondary outcome measures

Completion date

01/03/2011

Eligibility

Key inclusion criteria

Inclusion criteria group A/B:

1. Birth weight or birth length below -2 Standard Deviation (SD) adjusted for duration of pregnancy
2. Present height below -2.5 SD and at least 1 SD below target height-SD score
3. Calendar age between four and six 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 Growth Hormone (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 -SD score

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 (Target Height [TH] $\pm$ 1 SD)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

4 Years

Upper age limit

6 Years

Sex

Not Specified

Key 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 less than three 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 Growth Hormone Deficiency (GHD)
5. Medications or interventions during the previous six 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, Luteinising Hormone-Releasing Hormone (LHRH) analogue
7. Active or treated malignancy or increased risk of leukaemia
8. Serious suspicion of psychosocial dwarfism (emotional deprivation)
9. Severe neurological disability
10. Expected non-compliance
11. Prematurity less than 35 weeks
12. For Magnetoencephalography (MEG)/Magnetic Resonance Imaging (MRI) investigation: treatment with irremovable metal wires

Date of first enrolment

01/03/2007

Date of final enrolment

01/03/2011

Locations

Countries of recruitment

Netherlands

Study participating centre

VU Medisch Centrum

Amsterdam

Netherlands

1007 MB

Sponsor information

Organisation

Pfizer B.V. (The Netherlands)

ROR

<https://ror.org/02bzf1224>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

VU University Medical Centre (VUMC) (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration