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

Submission date	Recruitment status	[X] Prospectively registered
26/02/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
26/02/2007	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
26/08/2021	Nutritional, Metabolic, Endocrine	[ ] 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

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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).

Study design
Non-randomised parallel group trial

Primary study design
Interventional

Secondary study design
Single-centre

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
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 measures
No secondary outcome measures

Overall study start date
01/03/2007

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] ± 1 SD)

Participant type(s)
Patient

Age group
Child

Lower age limit
4 Years

Upper age limit
6 Years

Sex
Not Specified

Target number of participants
110

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)

Sponsor details
P.O. Box 37
Capelle a/d IJssel
Netherlands
2900 AA

Sponsor type
Industry

Website
http://www.pfizer.nl

ROR
https://ror.org/02bzf1224

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
VU University Medical Centre (VUMC) (The Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration