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Growth hormone treatment of children after IntraUterine Growth Retardation: IUGR-2 study

Submission date	Recruitment status	[ ] Prospectively registered
27/01/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
27/01/2006	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
29/12/2016	Pregnancy and Childbirth	

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

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NTR444

Study information

Scientific Title
Growth hormone treatment of children after IntraUterine Growth Retardation: IUGR-2 study

Acronym
IUGR-2 Study

Study objectives
Study evaluating the effects of growth hormone (GH)-therapy versus no GH therapy in children with short stature born after intrauterine growth retardation (IUGR) (age 3.00 tot 7.99 years).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from the local medical ethics committee

Study design
Multicentre randomised controlled parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Small for gestational age (SGA) children with persistent short stature

Interventions
Growth hormone treatment versus untreated control group.

For 3 years 2/3 of the children (n = 80) will be treated with biosynthetic growth hormone, 3 IU /m^2/day (GH-group), and 1/3 of the children (n = 40) will not receive growth hormone therapy (control group).

Children with GHD (max GH peak less than 20 mU/l during two GH stimulation tests) will not be randomised but will receive GH therapy from the start of the study (as a separate GHD group).

After 3 years the children of the control group will also start with GH therapy, 3 IU/m^2/day. GH therapy will be continued in all groups until attainment of final height. In 1999 a group of 30 older IUGR children (aged greater than 8 years) was added to the original protocol.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Growth hormone

Primary outcome measure
To assess the efficacy of biosynthetic GH treatment on various auxological parameters and bone maturation in comparison with a randomised untreated control group.

Secondary outcome measures
1. To assess the effects of biosynthetic GH treatment on bone density, lean body mass and daily food intake in comparison with a randomised untreated control group
2. To assess the long term efficacy of biosynthetic GH treatment on final height and other various auxological parameters
3. To assess the safety of GH treatment by studying the short- and long-term effects on blood pressure, carbohydrate metabolism, thyroid function

Overall study start date
17/12/1996

Completion date
31/12/2014

Eligibility

Key inclusion criteria
1. Birth weight less than P3 for gestational age (according to Usher and McLean)
2. Neonatal period without signs of severe asphyxia (defined by Apgar score less than 3 after 5 minutes), without signs of chronic lung disease (such as bronchopulmonary dysplasia)
3. No catch-up growth defined as obtaining a height of P3 within the first 2 years of life or at a later stage
4. Height velocity (cm/year) for chronological age P50
5. Chronological age at the start of treatment: 3.0 - 7.99 years (boys and girls)
6. Prepubertal signs defined as Tanner stage 1 or testicular volume less than 4 ml
7. Well documented growth data from birth up to 2 years and at least 1 year before the start of the study

Participant type(s)
Patient

Age group

Child

Lower age limit
3 Years

Upper age limit
7 Years

Sex
Both

Target number of participants
170

Key exclusion criteria
1. Any endocrine or metabolic disorder such as diabetes mellitus, diabetes insipidus, hypothyroidism or inborn errors of metabolism, except of GHD
2. Disorders of genito-urinary tract, cardiopulmonary or gastrointestinal tract, or nervous systems, nutritional and/or vitamin deficiencies
3. Chromosomal abnormalities or signs of a syndrome, except of Silver-Russell Syndrome (SRS)
4. Chondrodysplasia
5. Hydrocephalus
6. Active malignancy or increased risk of leukaemia
7. Serious suspicion of psychosocial dwarfism (emotional deprivation)
8. Previous anabolic sex steroid or GH therapy

Date of first enrolment
17/12/1996

Date of final enrolment
31/12/2014

Locations

Countries of recruitment
Netherlands

Study participating centre
Erasmus Medical Center
Rotterdam
Netherlands
3015 GJ

Sponsor information

Organisation
Erasmus Medical Centre (The Netherlands)

Sponsor details
Sophia Children's Hospital
Dr. Molewaterplein 60
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Sponsor type
Hospital/treatment centre

Website
http://www.erasmusmc.nl/content/englishindex.htm

ROR
https://ror.org/018906e22

Funder(s)

Funder type
Industry

Funder Name
Novo Nordisk (The Netherlands)

Alternative Name(s)
Novo Nordisk Global

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Denmark

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2017		Yes	No