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

Submission date	Recruitment status No longer recruiting	Prospectively registered	
27/01/2006		☐ Protocol	
Registration date	Overall study status Completed	Statistical analysis plan	
27/01/2006		[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

Contact name

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Contact details

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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

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 Rotterdam Netherlands 3015 GJ

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