Growth Hormone Treatment of Children after Intrauterine Growth Retardation.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27215

Source
NTR

Brief title
IUGR-2 Study

Health condition

Small for Gestational Age with persistent short stature

Sponsors and support

Primary sponsor: Prof. dr. A.C.S. Hokken-Koelega
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Source(s) of monetary or material Support: Novo Nordisk

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

1. To assess the effects of biosynthetic GH treatment on bone density, lean body mass and daily food intake in comparison with a randomized 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.

Study description

Background summary

Study evaluating the effects of GH-therapy versus no GH therapy in children with short stature born after intrauterine growth retardation (IUGR) (age 3.00 tot 7.99 years).
Randomisation of 120 children to one of the study groups after stratification for age and parental height.
During 3 years 2/3 of the children (n = 80) will be treated with biosynthetic growth hormone, 3 IU/m2/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 < 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/m2/day.
GH therapy will be continued in all groups until attainment of final height.
In 1999 a group of 30 older IUGR children (age > 8 years) was added to the original protocol.

Study objective

N/A

Intervention

Growth hormone treatment.

Contacts

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Eligibility criteria

Inclusion criteria

1. Birth weight < P3 for gestational age (according to Usher and Mc Lean);

2. Neonatal period without signs of severe asphyxia (defined as Apgar score < 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 ³ 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: 3.00 - 7.99 years (boys and girls);

6. Prepubertal signs defined as Tanner stage 1 or testicular volume < 4 ml;

7. Well documented growth data from birth up to 2 years and at least 1 year before the start of the study.

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-12-1996
Enrollment:	170
Type:	Actual

Ethics review

Positive opinion

Date:	14-09-2005
Application type:	First submission

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	NL404
NTR-old	NTR444
Other	: N/A
ISRCTN	ISRCTN96883876

Study results

Summary results

-Arends NJ, W VdL, Robben SG, Hokken-Koelega AC 2002 MRI findings of the pituitary gland in short children born small for gestational age (SGA) in comparison with growth hormone-deficient (GHD) children and children with normal stature. Clin Endocrinol (Oxf) 57:719-24

-Arends N, Johnston L, Hokken-Koelega A, et al. 2002 Polymorphism in the IGF-I gene: clinical relevance for short children born small for gestational age (SGA). J Clin Endocrinol Metab 87:2720

-Arends NJ, Boonstra VH, Mulder PG, et al. 2003 GH treatment and its effect on bone mineral density, bone maturation and growth in short children born small for gestational age: 3-year results of a randomized, controlled GH trial. Clin Endocrinol (Oxf) 59:779-87

-Boonstra V, van Pareren Y, Mulder P, Hokken-Koelega A 2003 Puberty in growth hormone-treated children born small for gestational age (SGA). J Clin Endocrinol Metab 88:5753-8
-Arends NJ, Boonstra VH, Hokken-Koelega AC 2004 Head circumference and body proportions before and during growth hormone treatment in short children who were born small for gestational age. Pediatrics 114:683-90
-Boonstra VH, Mulder PG, de Jong FH, Hokken-Koelega AC 2004 Serum dehydroepiandrosterone sulfate levels and pubarche in short children born small for gestational age before and during growth hormone treatment. J Clin Endocrinol Metab 89:712-7
--Arends NJ, Boonstra VH, Duivenvoorden HJ, Hofman PL, Cutfield WS, Hokken-Koelega AC 2005 Reduced insulin sensitivity and the presence of cardiovascular risk factors in short prepubertal children born small for gestational age (SGA). Clin Endocrinol (Oxf) 62:44-50
-Hokken-Koelega A, van Pareren Y, Arends N, Boonstra V. 2004 Efficacy and safety of long-term continuous growth hormone treatment of children born small for gestational age.
Horm Res. 62 Suppl 3:149-54. Review.
-Hokken-Koelega AC, De Waal WJ, Sas TC, Van Pareren Y, Arends NJ. Small for gestational age (SGA): endocrine and metabolic consequences and effects of growth hormone treatment. 2004
J Pediatr Endocrinol Metab. Mar;17 Suppl 3:463-9.
-Hokken-Koelega AC, van Pareren Y, Sas T, Arends N. 2003 Final height data, body composition and glucose metabolism in growth hormone-treated short children born small for gestational age.Horm Res. ;60 Suppl 3:113-4.