Growth Hormone Treatment of Children after Intrauterine Growth Retardation.

Gepubliceerd: 14-09-2005 Laatst bijgewerkt: 18-08-2022

N/A

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27215

Bron
NTR

Verkorte titel
IUGR-2 Study

Aandoening

Small for Gestational Age with persistent short stature

Ondersteuning

Primaire sponsor: Prof. dr. A.C.S. Hokken-Koelega
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Overige ondersteuning: Novo Nordisk

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

N/A

Onderzoeksproduct en/of interventie

Growth hormone treatment.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	17-12-1996
Aantal proefpersonen:	170
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	14-09-2005
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL404
NTR-old	NTR444
Ander register	: N/A
ISRCTN	ISRCTN96883876

Resultaten

Samenvatting resultaten

-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

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--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
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-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.