Growth Hormone Treatment of Children after Intrauterine Growth Retardation (IUGR-1 study).

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GH treatment of short, small-for-gestational-age children has a beneficial effect on linear growth.

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

Samenvatting

ID

NL-OMON26748

Bron
Nationaal Trial Register

Verkorte titel
IUGR-1 study

Aandoening

1. Small for gestational age (SGA);

2. Intrauterine growth retardation (IUGR).

Ondersteuning

Primaire sponsor: Novo Nordisk A/S, Denmark
Overige ondersteuning: Novo Nordisk A/S, Denmark

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. To assess the effect of GH therapy on:
a. linear growth;
b. bone maturation;
c. pubertal development;
d. final height;
in children with IUGR and no catch-up growth.

Toelichting onderzoek

Achtergrond van het onderzoek

Multicentred, double-blind, randomized, two-arm trial comparing two dose regimens of Norditropin® (a 2-year initial trial 14/NL and the trial extensions 20/NL (2-years) and 21/NL (till final height). In trial 14/NL, children were randomized to receive GH at either 3 IU (~1mg)/m2/day or 6 IU (~2mg)/m2/day for a 2-year treatment period. The children were stratified by age (3.00-5.99 years; 6.00-8.99 years; 9.00-10.99 years) and by their plasma 24-hour GH profile (normal GH insufficient, unknown).

Subjects who completed this trial continued in the trial extension 20/NL, and continued treatment, without interruption, in double-blind fashion at the dose level at which they were originally randomised.

Eleven older children who did not meet the criteria on age and puberty were included in a separate protocol. These children were treated according to protocol addendum GHRETARD/BPD/16/NL. Trial conduct in 16/NL was the same as that for 14/NL with the exception that all children received GH at 6 IU (~2mg)/m2/day. After two years of treatment, these children were allowed to continue in trial extension 20/NL.

Doel van het onderzoek

GH treatment of short, small-for-gestational-age children has a beneficial effect on linear growth.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Growth hormone treatment in either 3 or 6 IU (~1 or 2 mg)/m2/day (randomized double-blind dose-response trial).

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Birth length
2. Uncomplicated neonatal period, defined as no signs of:

a. severe asphyxia (Apgar score <3 after 5 minutes);

b. complicated sepsis neonatorum;

c. long-term complicated respiratory ventilation (for instance, bronchopulmonary dysplasia or pneumothorax);

3. No catch-up growth defined as obtaining a height of >= P3 (Roede), within the first two years of life or at a later stage;

4. Height velocity (HV) (cm/year) for chronological age <= P50 (Tanner);

5. Chronological age at start of treatment: girls: 3.00 to 8.99 years; boys: 3.00 to 10.99 years;

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

7. Well documented growth data from birth up to two years and at least one year before start of treatment;

8. Written informed consent from child and/or parents/guardians.

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);

2. Disorders of the genito-urinary tract, cardio-pulmonary or gastro-intestinal tract, or nervous system, nutritional and/or vitamin deficiencies;

3. Chromocomal abnormalities or signs of a syndrome, except for Silver-Russel syndrome;

4. Chondrodysplasia;

5. Hydrocephalus;

6. Subjects with active malignant diseases or with 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:	Dubbelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	24-10-1990
Aantal proefpersonen:	90
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	14-08-2007
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	NL1008
NTR-old	NTR1037
Ander register	:
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten

1. de Waal, W.J., Hokken-Koelega, A.C., Stijnen, T., de Muinck Keizer-Schrama, S.M. & Drop, S.L. (1994) Endogenous and stimulated GH secretion, urinary GH excretion, and plasma IGF-I and IGF-II levels in prepubertal children with short stature after intrauterine growth retardation. The Dutch Working Group on Growth Hormone. Clin Endocrinol (Oxf), 41, 621-630;
2. Sas, T., de Waal, W., Mulder, P., Houdijk, M., Jansen, M., Reeser, M. & Hokken-Koelega, A. (1999) Growth hormone treatment in children with short stature born small for gestational age: 5-year results of a randomized, double-blind, dose-response trial. J Clin Endocrinol Metab, 84, 3064-3070;
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4. Sas, T.C., Gerver, W.J., De Bruin, R., Mulder, P.G., Cole, T.J., De Waal, W. & Hokken-Koelega, A.C. (2000) Body proportions during 6 years of GH treatment in children with short stature born small for gestational age participating in a randomised, double-blind, dose-response trial. Clin Endocrinol (Oxf), 53, 675-681;
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6. van Pareren, Y., Mulder, P., Houdijk, M., Jansen, M., Reeser, M. & Hokken-Koelega, A. (2003) Effect of discontinuation of growth hormone treatment on risk factors for cardiovascular disease in adolescents born small for gestational age. J Clin Endocrinol Metab, 88, 347-353;
7. Van Pareren, Y., Mulder, P., Houdijk, M., Jansen, M., Reeser, M. & Hokken-Koelega, A. (2003) Adult height after long-term, continuous growth hormone (GH) treatment in short children born small for gestational age: results of a randomized, double-blind, dose-response GH trial. J Clin Endocrinol Metab, 88, 3584-3590;
8. van Pareren, Y.K., Duivenvoorden, H.J., Slijper, F.S., Koot, H.M. & Hokken-Koelega, A.C. (2004) Intelligence and psychosocial functioning during long-term growth hormone therapy in children born small for gestational age. J Clin Endocrinol Metab, 89, 5295-5302;
9. Bannink, E.M., van Pareren, Y.K., Theunissen, N.C., Raat, H., Mulder, P.G. & Hokken-Koelega, A.C. (2005) Quality of life in adolescents born small for gestational age: does growth hormone make a difference? Horm Res, 64, 166-174;
10. Bannink, E.M., van Doorn, J., Mulder, P.G. & Hokken-Koelega, A.C. (2007) Free/Dissociable Insulin-Like Growth Factor (IGF)-I, Not Total IGF-I, Correlates with Growth Response during Growth Hormone Treatment in Children Born Small for Gestational Age. J Clin Endocrinol Metab, 92, 2992-3000.