A study on the Tissue Responsiveness to short term exogenous GH in children with idiopathic short stature in relation to their reponse to long-term treatment.

No registrations found.

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

Summary

ID

NL-OMON24302

Source
NTR

Brief title
Dose-response study

Health condition

Children with idiopathic short stature (ISS)

Sponsors and support

Primary sponsor: Pfizer (New York) (previously Pharmacia), through local representatives in the Netherlands.
Source(s) of monetary or material Support: NWO (Netherlands Medical Research Council)

Intervention

Outcome measures

Primary outcome

Height at stop of therapy (at onset of puberty) and final height.

Secondary outcome

1. Timing of onset of puberty;
- duration of puberty;

2. Relation between long-term growth response (dependent variable) and short-term growth response on various dosages and in vitro responsiveness of cultured skin fibroblasts to GH and IGF-I;

3. Effect of GH therapy on quality of life.

Study description

Background summary

The predictive power of the diagnostic phase (dose-response relationship, in vitro responsiveness of skin fibroblasts) is limited. GH accelerates puberty onset and duration. No clear effect on quality of life was found.

Study objective

The change in biochemical parameters of bone and colleagen metabolism during a shortterm GH dose-response study predicts the long-term effect of GH on growth. Idiopathic short stature is partially explainable by an abnormal tissue responsiveness to GH and IGF-I. GH theray in a dosage of 6 IU//mw.day administered before puberty increases height velocity, height in adolescence and final height. GH administration affects puberty onset and its duration. GH administration affects quality of life.

Intervention

After randomisation, the control group did not receive treatment, and were followed yearly for growth and puberty assessment.
The treatment group underwent two 3 months periods of GH administration (1.5 IU/m2.d, 3.0 IU/m2.d) with 3 months washout periods in between. Thereafter 6 IU/m2.d was given until the beginning of puberty.

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Eligibility criteria

Inclusion criteria

40 children. Height SDS<-2, prepubertal, age 4-8 (F) or 4-10 (M), GH response to provocation tests >20 mU/l, normal sitting height.height ratio, normal screening blood tests and urinanalysis.

Exclusion criteria

Any systemic disease during childhood that limits the growth potential or may interfere with the evaluation of the effectiveness of therapy.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)

Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-1994
Enrollment:	40
Type:	Actual

Ethics review

Positive opinion

Date:	12-09-2005
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	NL342
NTR-old	NTR380
Other	: N/A
ISRCTN	ISRCTN52337368

Study results

Summary results

Kamp, G.A., Rekers-Mombarg L.T.M., Wit, J.M. Does GH treatment affect pubertal timing in children with idiopathic short stature? Highlights 1997;5:12-15. 205.
 Kamp, G.A., Wit, J.M. High-dose growth hormone therapy in idiopathic short stature. Horm Res 1998;49 (suppl 2):67-72. 238.
Rekers-Mombarg, L.T.M., Kamp, G.A., Massa, G.G., Wit, J.M. Influence of growth hormone treatment on pubertal timing and pubertal growth in children with idiopathic short stature. J Pediatr Endocrinol Metab 1999;12 (5):611-622 287.
Theunissen N.C.M., Kamp, G.A., Koopman, H.M., Zwinderman, K.A.H., Vogels, M.A., Wit, J.M. Quality of life and self esteem in children treated for idiopathic short stature. J.Pediatrics, 2002;140:507-15 288.
Kamp, G.A. Waelkens, J.J.J., De Muinck Keizer-Schrama, S.M.P.F., Delemarre-van de Waal, H.A., Verhoeven-Wind, L., Wit, J.M. High dose growth hormone treatment induces acceleration of skeletal maturation and an earlier onset of puberty in children with idiopathic short stature. Arch Dis Child, 2002;87:215-220289.
Kamp, G.A., Ouwens, D.M., Hoogerbrugge, C.M., Zwinderman, A.H., Maassen, J.A., Wit, J.M. Skin fibroblasts of children with idiopathic short stature show an increased mitogenic response to IGF-I and secrete more IGFBP-3 compared to normal children. Clin Endocrinol 2002;56:439-447 294.
Kamp, G.A. , Zwinderman, A.H., Doorn, J. van, Hackeng, W., Frölich, M., Schönau, E., Wit, J.M. Biochemical markers of growth hormone (GH) sensitivity in children with idiopathic short stature: individual capacity of IGF-I generation after high dose GH treatment determines the growth response to GH. Clin Endocrinol 2002; 57:315-325