ISRCTN57632130 https://doi.org/10.1186/ISRCTN57632130

The prevalence of growth hormone deficiency in autoimmune thyroid disease

Submission date	Recruitment status	[ ] Prospectively registered
22/11/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
22/11/2006	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
18/07/2008	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr S A Eskes

Contact details
Academic Medical Center (AMC),
Department of Endocrinology,
P.O. Box 22660
Amsterdam
Netherlands
1100 DD
+31 (0)20 5669111
S.A.Eskes@amc.uva.nl

Additional identifiers

Protocol serial number
NTR755

Study information

Scientific Title

Study objectives
The prevalence of growth hormone deficiency in autoimmune thyroid disease is higher than in the general population.

Please note that as of 07/07/2008 the sources of funding section of this trial was updated. For details of this change, please go to the sources of funding section of this record. On 18/07/2008, the interventions section was also updated.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee (Medisch Ethische Toetsings Commissie of the Academic Medical Center Amsterdam) on the 15th December 2005 (ref: MEC 05/249)

Study design
Observational cross-sectional study

Primary study design
Observational

Study type(s)
Screening

Health condition(s) or problem(s) studied
Autoimmune hypothyroidism

Interventions
Investigating the prevalence is of growth hormone deficiency in patients with autoimmune hypothyroidism.

Added 18/07/2008:
Insulin-like growth factor I (IGF-I) values were measured from a blood sample. If the IGF-I value was beneath the 10th percentile of the reference values, a growth-hormone-releasing hormone (GHRH)/growth-hormone-releasing peptide 6 (GHRP-6) test was performed.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Prevalence of growth hormone deficiency in patients with autoimmune hypothyroidism, measured a the first visit and when the second test is necessary at a second visit that is planned a few weeks later.

Key secondary outcome(s))
Quality of life in patients with autoimmune hypothyroidism with or without growth hormone deficiency.

Completion date
01/07/2008

Eligibility

Key inclusion criteria
1. Autoimmune hypothyroidism
2. Adequate thyroxine treatment
3. Aged between 20 and 70 years old, both men and women

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. History of hypothalamic or pituitary disease or known growth hormone deficiency
2. Pregnancy
3. Hypothyroidism after treatment for Graves' disease or surgery or radioactive iodine (I131)
4. Major concurrent diseases
5. Use of medications known to interfere with the growth hormone-Insulin-like Growth Factor-I (IGF-1) axis
6. No informed consent
7. Alcohol or drug abuse

Date of first enrolment
01/08/2006

Date of final enrolment
01/07/2008

Locations

Countries of recruitment
Netherlands

Study participating centre

Academic Medical Center (AMC),
Amsterdam
Netherlands
1100 DD

Sponsor information

Organisation
Academic Medical Center (AMC) (The Netherlands)

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Industry

Funder Name
Added as of 07/07/2008:

Funder Name
Ipsen Pharmaceutica BV (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration