

The prevalence of growth hormone deficiency in autoimmune thyroid disease

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Cross-section survey

Study setting(s)

Not specified

Study type(s)

Screening

Participant information sheet

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 measure

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

Secondary outcome measures

Quality of life in patients with autoimmune hypothyroidism with or without growth hormone deficiency.

Overall study start date

01/08/2006

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

Age group

Adult

Sex

Both

Target number of participants

600

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)

Sponsor details

Department of Endocrinology and Metabolism

P.O. Box 22660

Amsterdam

Netherlands

1100 DD

Sponsor type

Hospital/treatment centre

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**Publication and dissemination plan**

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration