

The prevalence of growth hormone deficiency in autoimmune thyroid disease

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

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)

Primary study design

Observational

Study design

Observational cross-sectional study

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 at 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