Combined treatment with thyroxine plus triiodothyronine for primary hypothyroidism in humans

Submission date	Recruitment status	Prospectively registered
23/08/2004	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
28/07/2005	Completed	Results
Last Edited	Condition category	Individual participant data
21/05/2008	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

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Contact details

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Additional identifiers

Protocol serial number PI27/99

Study information

Scientific Title

Study objectives

Not provided at time of registration

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Hypothyroidism

Interventions

A randomized double-blind crossover design served to compare treatment with 100 µg of levothyroxine per day and treatment with a combination containing 75 µg of levothyroxine plus 5 µg of liothyronine per day, in periods of 8 weeks each. All the patients were also given a combination containing 87.5 µg of levothyroxine plus 7.5 µg of liothyronine per day for a final 8-week period add-on.

The function of the euthyroid healthy external control group was:

- 1. To evaluate the clinical meaningfulness of any changes detected between treatments in hypothyroid patients, given that subtle differences may be observed, but could not be important if patients were comparable to healthy people when on both treatments
- 2. To evaluate if patients perform worse than controls irrespective of the treatment applied

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Levothyroxine, liothyronine

Primary outcome(s)

Not provided at time of registration

Key secondary outcome(s))

Not provided at time of registration

Completion date

Eligibility

Key inclusion criteria

Inclusion criteria required women between 18 and 70 years-old, presenting with overt primary hypothyroidism as defined by increased thyroid-stimulating hormone (TSH) and decreased free T4 serum levels at diagnosis, who maintained serum TSH levels within the normal range on a stable levothyroxine dose of 100 µg per day for at least the previous year.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Female

Key exclusion criteria

Exclusion criteria included mental illnesses, affective disorders or use of psychotropic drugs, cardiovascular, renal or hepatic disease, osteoporosis, and treatment with drugs that may interfere with thyroid function other than levothyroxine.

The external euthyroid control group was composed of healthy women.

Date of first enrolment

01/04/2000

Date of final enrolment

31/05/2005

Locations

Countries of recruitment

Spain

Study participating centre Department of Endocrinology

Madrid Spain 28034

Sponsor information

Organisation

Hospital Ramón y Cajal, Madrid (Spain)

ROR

https://ror.org/050eq1942

Funder(s)

Funder type

Industry

Funder Name

Predoctoral fellowships from the Consejería de Educación, Comunidad de Madrid (01/0430/01), and from the Fondo de Investigación Sanitaria (01/F072), Instituto de Salud Carlos III, Ministerio de Sanidad y Consumo, Spain, to one of the Authors. Financial aid came from Merck Darmstad KgaA, Germany.

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration