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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
Dr Héctor F Escobar-Morreale

Contact details
Department of Endocrinology
Hospital Ramón y Cajal
Carretera de Colmenar km 9,1
Madrid
Spain
28034

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/04/2000

Completion date
31/05/2005

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

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
Not provided at time of registration

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)

Sponsor details
Carretera de Colmenar km 9,1
Madrid
Spain
28034

Sponsor type
Hospital/treatment centre

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

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