

# Combined treatment with thyroxine plus triiodothyronine for primary hypothyroidism in humans

<b>Submission date</b> 23/08/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 28/07/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 21/05/2008	<b>Condition category</b> 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

**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

**Primary study design**

Interventional

**Study design**

Randomised controlled trial

**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**

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

### 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

Predocctoral 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