# CHATS: Central Hypothyroidism And Adjusted Thyroxine Dose Study (Chats): Impact Of Increasing Free Thyroxine Levels In Patients With Hypopituitarism

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
29/09/2006	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
29/09/2006	Completed	[X] Results
<b>Last Edited</b> 17/01/2012	<b>Condition category</b> Nutritional, Metabolic, Endocrine	Individual participant data
1//01/2012	Muchicional, Metabolic, Endocrine	

## 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

N0063173623

# Study information

## Scientific Title

## **Study objectives**

Primary objective of the study: impact of increased thyroxine supplementation on quality of life.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Not provided at time of registration

## Study design

Randomised, double-blind, placebo-controlled study

## Primary study design

Interventional

## Study type(s)

Quality of life

## Health condition(s) or problem(s) studied

Nutritional, Metabolic, Endocrine: Hypopituitarism

## **Interventions**

Arm A: Thryoxine Arm B: Placebo

## Intervention Type

Drug

## **Phase**

**Not Specified** 

## Drug/device/biological/vaccine name(s)

Thryoxine

## Primary outcome(s)

QoL assessment with:

- 1. PGWB (Psychological General Well-Being Schedule)
- 2. SF-36 (Medical Outcomes Study Short Form36)
- 3. EQ-5D (EuroQol EQ-5D) and questionnaires

## Key secondary outcome(s))

- 1.Thyroid-specific symptom questionnaire
- 2. QoL assessment with QoL-AGHDA
- 3. BP, HR
- 4. fT4, fT3, TSH

- 5. CK, SHBG
- 6. Fasting TC, LDL-C, HDL-C, Lp(a)
- 7. Body composition, BMI
- 8. ECG and 24 hour Holter ECG
- 9. Carotid intima-media thickness measurement

## Completion date

31/12/2008

# Eligibility

## Key inclusion criteria

Patients (aged 20-70) with hypopituitarism and low-normal free thyroxine levels.

## Participant type(s)

Patient

## Healthy volunteers allowed

No

## Age group

Adult

#### Sex

**Not Specified** 

## Key exclusion criteria

- 1. Age <20 or >70 years
- 2. Inability to give informed consent
- 3. Obvious or suspected poor compliance
- 4. Thyrotoxicosis
- 5. Severe concomitant illness with significant impact on life expectancy
- 6. Active acromegaly or Cushing's disease
- 7. Uncontrolled cardiac arrhythmias or unstable ischaemic heart disease
- 8. Treatment with Amiodarone or Lithium within the last 6 months
- 9. Current treatment with: L-Tri-iodothyronine, Carbimazole, Propylthiouracil

## Date of first enrolment

23/09/2005

## Date of final enrolment

31/12/2008

# Locations

## Countries of recruitment

United Kingdom

England

# Study participating centre Endocrinology

Manchester United Kingdom M20 4BX

# Sponsor information

## Organisation

Record Provided by the NHSTCT Register - 2006 Update - Department of Health

# Funder(s)

## Funder type

Government

## **Funder Name**

Christie Hospital NHS Trust

## **Funder Name**

NHS R&D Support Funding

# **Results and Publications**

Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration

# **Study outputs**

Output type	Details	Date created Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2007	Yes	No
Participant information sheet	Participant information sheet	11/11/2025 11/11/2025	No	Yes