

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

**Submission date**

29/09/2006

**Recruitment status**

No longer recruiting

**Registration date**

29/09/2006

**Overall study status**

Completed

**Last Edited**

17/01/2012

**Condition category**

Nutritional, Metabolic, Endocrine

☐ Prospectively registered

☐ Protocol

☐ Statistical analysis plan

☒ Results

☐ Individual participant data

**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

EudraCT/CTIS number

IRAS number

**ClinicalTrials.gov number**

**Secondary identifying numbers**

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

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Not specified

**Study type(s)**

Quality of life

**Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

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

Nutritional, Metabolic, Endocrine: Hypopituitarism

**Interventions**

Arm A: Thyroxine

Arm B: Placebo

**Intervention Type**

Drug

**Phase**

Not Specified

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

Thyroxine

**Primary outcome measure**

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

**Secondary outcome measures**

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

**Overall study start date**

23/09/2005

**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

**Age group**

Adult

**Sex**

Not Specified

**Target number of participants**

A total of 80 patients are required for the trial.

**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**

England

United Kingdom

**Study participating centre****Endocrinology**

Manchester

United Kingdom

M20 4BX

## Sponsor information

**Organisation**

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

**Sponsor details**

The Department of Health, Richmond House, 79 Whitehall

London

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SW1A 2NL

+44 (0)20 7307 2622

dhmail@doh.gsi.org.uk

**Sponsor type**

Government

**Website**

<http://www.dh.gov.uk/Home/fs/en>

## Funder(s)

**Funder type**

Government

**Funder Name**

Christie Hospital NHS Trust

**Funder Name**

NHS R&D Support Funding

## 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

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/01/2007		Yes	No