

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	<input type="checkbox"/> Prospectively registered
Registration date 29/09/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 17/01/2012	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

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
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: Thyroxine

Arm B: Placebo

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Thyroxine

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