

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

Prof S M Shalet

Contact details

Endocrinology
Christie Hospital NHS Trust
Wilmslow Road
Withington
Manchester
United Kingdom
M20 4BX
+44 0161 446 3667
stephen.m.shalet@man.ac.uk

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

United Kingdom

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?
Results article	results	01/01/2007		Yes	No