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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
[X] 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
Wilsmlow Road
Withington
Manchester
United Kingdom
M20 4BX
+44 0161 446 3667
stephen.m.shalet@man.ac.uk

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

Primary study design
Interventional

Study design
Randomised, double-blind, placebo-controlled study

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