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Study of optimal replacement of thyroxine in the elderly

Submission date	Recruitment status	[X] Prospectively registered
22/06/2012	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
22/06/2012	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
24/10/2016	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2011-004425-27

IRAS number

ClinicalTrials.gov number
NCT01647750

Secondary identifying numbers
12397

Study information

Scientific Title
Study of Optimal Replacement of Thyroxine in the ElDerly (SORTED)

Acronym
SORTED

Study objectives
All patients with hypothyroidism are currently treated the same way, regardless of age. We want to look at whether people aged 80 years or older would benefit from being treated with lower doses of levothyroxine. There are three reasons why we think this could be beneficial, but this is not yet proven:
1. Some older people with hypothyroidism may have few symptoms.
2. Doctors look at the amount of Thyroid Stimulating Hormone (TSH) in the patients blood to decide the dose of Thyroxine received. The standard normal TSH range used to determine the dose of levothyroxine is from younger people. We wonder whether this is appropriate to all age ranges particularly as we know that older people may normally have higher TSH values.
3. If TSH levels are too low there may be a slight increased risk of problems such as brittle bones or an irregular heartbeat.

The best way to test whether older people benefit from lower doses of levothyroxine is by a large clinical trial. Before we can do this, we need to run a smaller clinical trial called a pilot study (SORTED 1) to examine whether this is practical and acceptable. The pilot study aims to recruit 50 patients with hypothyroidism aged 80 or above.

Participants will be randomly allocated to receive their routine or lower dose of levothyroxine. Follow-up will be conducted over approximately 25 weeks.

We also propose a qualitative study (SORTED 2) to specifically understand patients willingness to take part in a RCT and participants experience of the intervention.

Finally, we propose a retrospective cohort study of 400 treated hypothyroid patients aged 80 years or more registered in 2008 in Primary Care Practices with the aim of studying outcomes after 4 years. The cohort study will collect data required to inform a sample size calculation for a future full study where the primary outcome will be 4 year mortality.

Ethics approval required
Old ethics approval format

Ethics approval(s)
12/NE/0098

Study design
Interventional and Observational; Design type: Treatment, Cohort study

Primary study design
Interventional

Secondary study design

Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Topic: Primary Care Research Network for England, Metabolic and Endocrine; Subtopic: Not Assigned, Metabolic and Endocrine (all Subtopics); Disease: Metabolic & Endocrine (not diabetes), All Diseases

Interventions
Patients will be randomised to receive either standard or lower dose dose Levothyroxine

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome measure
Patients willingess to participate and acceptability of study design; Timepoint(s): For the duration of the SORTED 1 study

Secondary outcome measures
1. Assessment of change in specific cardiovascular risk factors
2. Assessment of dose titration strategy
3. Assessment of length of time to achieve desired TSH level
4. Assessment of mobility and risk of falls in this population group
5. Assessment of participant recruitment rate; Timepoint(s): Over the duration of the SORTED 1 study, until last patient is randomised; Assessment of 6. Use of quality of life questionnaires

Assessed over the duration of the SORTED 1 study

Overall study start date
01/07/2012

Completion date
30/06/2013

Eligibility

Key inclusion criteria
1. Males and females aged 80 years or older
2. Diagnosed with hypothyroidism and treated with LT4 for at least 6 months
3. Living independently in the community
4. All TSH results within the range 0.4 - 4mU/L in the 3 months before commencing the study
5. Participant has provided written informed consent for participation in the study, prior to any study-specific procedures

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
Planned Sample Size: 68; UK Sample Size: 68

Key exclusion criteria
1. Established dementia and therefore deemed incapable of providing informed consent.
2. Other medical conditions which, in the opinion of the Chief Investigator, would prevent them from participating in the study (for example, end stage cancer, severe chronic health conditions where the patient is housebound)
3. Nursing Homes or Residential Care Home residents
4. Individuals with thyroid cancer: since they require high doses of LT4 to suppress their serum TSH
6. Individuals on 25 mcg daily of LT4: dose reduction will mean that they stop thyroid replacement treatment
7. Non English speaking individuals
8. Participation in any other investigational trials within the last 3 months
9. Participants prescribed medications that can affect thyroid function (amiodarone, lithium, carbimazole or propylthiouracil)
10. Known or suspected lactose intolerance (this would have implications for the proposed over-encapsulated IMP)

Date of first enrolment
01/07/2012

Date of final enrolment
30/06/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
4th Floor William Leech Building
Newcastle Upon Tyne
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Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

Sponsor details
Leazes Wing, Royal Victoria Infirmary
Queen Victoria Road
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Sponsor type
Charity

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

United Kingdom

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?
Protocol article	protocol	22/03/2013		Yes	No
Results article	results	10/10/2016		Yes	No
HRA research summary			28/06/2023	No	No