

# Study of optimal replacement of thyroxine in the elderly

<b>Submission date</b> 22/06/2012	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 22/06/2012	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Protocol
<b>Last Edited</b> 24/10/2016	<b>Condition category</b> 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

**ClinicalTrials.gov (NCT)**  
NCT01647750

**Clinical Trials Information System (CTIS)**  
2011-004425-27

**Protocol serial number**  
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

## Study type(s)

Treatment

**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(s)**

Patients willingness to participate and acceptability of study design; Timepoint(s): For the duration of the SORTED 1 study

**Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

## **Age group**

Senior

## **Sex**

All

## **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**

United Kingdom

England

### **Study participating centre**

**4th Floor William Leech Building**

Newcastle Upon Tyne

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NE2 4HH

## **Sponsor information**

### **Organisation**

Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

## 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

### 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	10/10/2016		Yes	No
<a href="#">Protocol article</a>	protocol	22/03/2013		Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No