UK Trial of Radioiodine Intervention in Subclinical Hyperthyroidism

Submission date	Recruitment status	[X] Prospectively registered	
16/12/2005	No longer recruiting	☐ Protocol	
Registration date	Overall study status	Statistical analysis plan	
08/08/2006	Completed	[X] Results	
Last Edited	Condition category	[] Individual participant data	
13/11/2017	Nutritional, Metabolic, Endocrine		

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

G0500783

Study information

Scientific Title

UK Trial of Radioiodine Intervention in Subclinical Hyperthyroidism

Acronym

TRISH

Study objectives

Radioiodine treatment for sustained subclinical hyperthyroidism will not reduce circulatory endpoints in the elderly.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval gained from the Newcastle and North Tyneside Research Ethics Committee (reference number: 06/Q0905/112).

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Subclinical hyperthyroidism

Interventions

Radioiodine treatment versus usual care.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Radioiodine

Primary outcome measure

Composite circulatory mortality

Secondary outcome measures

- 1. All cause mortality
- 2. Atrial fibrillation
- 3. Progression to overt

hyperthyroidism

- 4. Hip and vertebral fractures
- 5. MMTS

Overall study start date

01/10/2006

Completion date

30/09/2015

Eligibility

Key inclusion criteria

- 1. Over 65 years of age
- 2. Sustained subclinical hyperthyroidism (undetectable Thyroid Stimulating Hormome [TSH], normal free thyroid

hormones) for greater than three months

Participant type(s)

Patient

Age group

Senior

Sex

Both

Target number of participants

780

Key exclusion criteria

- 1. Patient currently has or has ever had Atrial Fibrillation (AF)
- 2. Certain drug usage
- 3. Pituitary, severe renal or hepatic disease
- 4. Unstable coronary disease

Date of first enrolment

01/10/2006

Date of final enrolment

30/09/2015

Locations

Countries of recruitment

England

United Kingdom

Study participating centre School of Clinical Medical Sciences Newcastle upon Tyne United Kingdom NE2 4HH

Sponsor information

Organisation

Newcastle upon Tyne Hospitals NHS Trust (UK)

Sponsor details

Research and Development Department Clinical Research Facility Leazes Wing, 4th Floor Royal Victoria Infirmary Newcastle upon Tyne England United Kingdom NE1 4LP

Sponsor type

Hospital/treatment centre

ROR

https://ror.org/05p40t847

Funder(s)

Funder type

Research council

Funder Name

Medical Research Council (UK)

Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, MRC

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?
Results article	results	01/05/2008		Yes	No