# ION - Is ablative radiOiodine Necessary for low risk differentiated thyroid cancer patients?

Submission date	Recruitment status No longer recruiting	<ul><li>[X] Prospectively registered</li><li>Protocol</li></ul>		
11/01/2011				
Registration date	Overall study status Ongoing	Statistical analysis plan		
03/03/2011		[X] Results		
Last Edited	Condition category	[] Individual participant data		
24/06/2025	Cancer			

# Plain English summary of protocol

http://cancerhelp.cancerresearchuk.org/trials/a-trial-to-see-if-radioactive-iodine-treatment-is-necessary-for-low-risk-thyroid-cancer-ion

# Contact information

# Type(s)

Scientific

#### Contact name

Ms Emily Ambrose

#### Contact details

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# Additional identifiers

Clinical Trials Information System (CTIS)

2011-000144-21

Integrated Research Application System (IRAS)

75777

ClinicalTrials.gov (NCT)

NCT01398085

#### Protocol serial number

UCL/10/0299, IRAS 75777

# Study information

#### Scientific Title

Randomised trial comparing total thyroidectomy, thyriod stimulating hormone (TSH) suppression and radioactive iodine ablation with total thyroidectomy and TSH suppression, in low-risk patients with thyroid cancer

## Acronym

ION

## Study objectives

Phase II:

To determine if recruitment into a phase III trial is feasible, with a target of 10 patients per month during a minimum period of 6 months (evaluated within months 7 - 18 of the trial).

#### Phase III:

To determine whether the 5-year recurrence-free survival rate among patients who do not have routine radioactive iodine (RAI) ablation is non-inferior to those that do.

As of 06/06/2012, the following changes have been made to the trial.

Anticipated start date has been updated from 02/05/2011 to 16/05/2012.

Anticipated end date has been updated from 05/05/2015 to 16/05/2021 (includes recruitment and follow up phase).

Target number of participants has been increased from 550 to 570.

# Ethics approval required

Old ethics approval format

# Ethics approval(s)

Added as of 06/06/2012

North East - Newcastle and Tyneside REC approved on 15/09/2011 (ref: 11/NE/0228)

Birmingham Research Ethics Committee (REC) approval pending as of 12/01/2011

# Study design

Randomized non-blind non-inferiority Phase II/III multicentre trial

# Primary study design

Interventional

# Study type(s)

Treatment

# Health condition(s) or problem(s) studied

Differentiated thyroid cancer

#### **Interventions**

Following surgery, eligible patients will be approached for consent. Those who agree will be randomised to one of the following groups:

- 1. Radioactive iodine (RAI) ablation arm (1.1 GBq), or
- 2. No radioactive iodine (NO-RAI) ablation arm

Total duration of treatment will be from randomisation to last scan (8 - 9 months), and follow-up will be for 5 years.

Chief investigator contact details:

Dr Ujjal Mallick Freeman Road High Heaton Newcastle NE7 7DN

## Intervention Type

Drug

## Phase

Phase II/III

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

Radioactive iodine

## Primary outcome(s)

- 1. Phase II: monthly patient accrual rates, evaluated 7 18 months after the start. There will then be a decision on whether to proceed to phase III or not
- 2. Phase III: 5-year recurrence-free survival, evaluated after the last patient has their last followup or sooner depending on the data

# Key secondary outcome(s))

Current secondary outcome measure (s) as of 06/06/2012:

Phase III only (evaluated by the statistician at the final analysis at the end of the study):

- 1. Quality of life (E5-QD, QLQ-C30, H&N35)
- 2. Adverse events (Common Toxicity Criteria for Adverse Events [CTCAE])
- 3. Thyroid cancer mortality
- 4. Loco-regional recurrence
- 5. Distant metastases
- 6. Incidence of second primary tumours

Analysis will depend on recruitment but if the trial goes to phase III we expect all patients to be recruited in 3 - 4 years so last visit and analysis will be 8-9 years after the start.

Previous secondary outcome measure (s):

Phase III only (evaluated by the statistician at the final analysis at the end of the study):

- 1. Quality of life (E5-QD and SF-36)
- 2. Adverse events (Common Toxicity Criteria for Adverse Events [CTCAE])
- 3. Thyroid cancer mortality
- 4. Loco-regional recurrence
- 5. Distant metastases
- 6. Incidence of second primary tumours

Analysis will depend on recruitment but if the trial goes to phase III we expect all patients to be recruited in 3 - 4 years so last visit and analysis will be 8-9 years after the start.

# Completion date

31/03/2031

# **Eligibility**

## Key inclusion criteria

Current inclusion criteria as of 06/06/2012

- 1. R0 total thyroidectomy (in 1 or 2 stages, no residual disease present)
- 2. Negative pregnancy test in females of child bearing potential
- 3. Aged 16 years or over
- 4. WHO performance status 0 2, self caring
- 5. Histological confirmation of differentiated thyroid carcinoma
- 6. Papillary thyroid cancer:
- 6.1 Non agressive histological features (small foci of agressive histology allowed)
- 6.2 pT1b, 1-2cm intrathyroidal
- 6.3 pT2, 2-4cm intrathyroidal
- 6.4 pT3 intrathyroidal only
- 6.5 Multifocal carcinoma
- 6.6 pN0
- 6.7 pN1a
- 6.8 pNX
- 7. Follicular thyroid cancer/Hürthle cell cancer (minimally invasive with capsular invasion only
- 7.1 pT1b (1-2cm) pT2 (2-4cm) intrathyroidal

#### Previous inclusion criteria

- 1. Negative pregnancy test in females of child bearing potential
- 2. Aged 16 years or over, either sex
- 3. World Health Organization (WHO) performance status 0 2
- 4. R0 total thyroidectomy (in 1 or 2 stages, no residual disease present)
- 5. Histological confirmation of differentiated thyroid carcinoma
- 6. Papillary thyroid cancer:
- 6.1. Non aggressive histological features (small foci allowed)
- 6.2. T1b, 1 2 cm, intrathyroidal
- 6.3. T2, 2 4 cm, intrathyroidal
- 6.4. T3, intrathyroidal
- 6.5. No vascular invasion
- 6.6. Multifocal microcarcinoma
- 6.7. NO
- 6.8. N1a
- 6.9. NX
- 7. Follicular thyroid cancer/Hürthle cell cancer:
- 7.1. Minimally invasive (capsular invasion only)
- 7.2. Tumours 2 cm or less
- 7.3. NO
- 7.4. N1a
- 7.5. NX

# Participant type(s)

#### Patient

## Healthy volunteers allowed

No

## Age group

Adult

## Lower age limit

16 years

#### Sex

All

#### Total final enrolment

504

# Key exclusion criteria

Current exclusion criteria as of 06/06/2012

- 1. Papillary and Follicular carcinoma which is unifocal and <1cm in size
- 2. Encapsulated Follicular Variant of Papillary Thyroid Cancer (EFVPTC) that is:
- 2.1. non-invasive
- 2.2. angio-invasive
- 3. Anaplastic or medullary carcinoma
- 4. R1 thyroidectomy
- 5. Patients with:
- 5.1 pN1b
- 5.2 M1
- 6. Aggressive Papillary thyroid cancer with the following features:
- 6.1 Angio-invasive
- 6.2 Widely invasive
- 6.3 Poorly differentiated
- 6.4 Anaplastic differentiation
- 6.5 Tall cell
- 6.6 Columnar cell
- 6.7 Diffuse sclerosing variants
- 7. Follicular thyroid cancer/Hürthle cell cancer with the following features:
- 7.1. Angio-invasive
- 7.2. Widely invasive
- 7.3. Poorly differentiated
- 7.4. Tumours greater than 4cm
- 8. Incomplete resection/lobectomy
- 9. Macroscopic and microscopic tumour invasion of locoregional tissues or structures
- 10. Women who are lactating
- 11. Patients who have had CT performed with iv contrast less than 3 months before ablation
- 12. Previous treatment for thyroid cancer (except surgery)
- 13. Previous malignancies with limited life expectancy or likely to interfere with the patient's ability to be able to comply with treatment and/or follow-up for at least 5 years
- 14. Dysphagia
- 15. Oesophageal stricture
- 16. Active gastritis

- 17. Gastric erosions
- 18. Peptic ulcer
- 19. Suspected reduced gastrointestinal motility
- 20. Severe co-morbid condition/s that would prevent ablation including:
- 20.1. Unstable angina
- 20.2. Recent myocardial infarction or cerebrovascular accident (CVA)
- 20.3. Severe labile hypertension
- 21. Any patient who cannot comply with radiation protection including:
- 21.1. patients with learning difficulties
- 21.2. patients with dementia
- 21.3. patients with a tracheostomy that require nursing care
- 21.4. patients requiring frequent nursing/medical supervision

#### Previous exclusion criteria

- 1. Pregnant women or women who are breastfeeding
- 2. Patients who have computed tomography (CT) performed with intravenous (iv) contrast less than 3 months before ablation
- 3. Previous treatment for thyroid cancer (not including surgery)
- 4. Incomplete resection/lobectomy
- 5. Local or distant metastases at diagnosis
- 6. Macroscopic and microscopic tumour invasion of locoregional tissues or structures
- 7. Anaplastic or medullary carcinoma
- 8. Patients with:
- 8.1. N1b
- 8.2. M1
- 9. Previous malignancies with limited life expectancy likely to interfere with the patient's ability to be able to comply with treatment and/or follow-up
- 10. Severe co-morbid condition/s that would prevent ablation including:
- 10.1. Unstable angina
- 10.2. Recent myocardial infarction or cerebrovascular accident (CVA)
- 10.3. Severe labile hypertension
- 10.4. Any patient who cannot comply with radiation protection including:
- 10.4.1. Patients with learning difficulties
- 10.4.2. Patients with dementia
- 10.4.3. Patients with a tracheotomy that require nursing care
- 10.4.4. Patients requiring frequent nursing/medical supervision
- 11. Papillary thyroid cancer that is:
- 11.1. Widely invasive
- 11.2. Poorly differentiated
- 11.3. Tall cell
- 11.4. Columnar cell
- 11.5. Diffuse sclerosing variants
- 12. Follicular thyroid cancer/Hürthle cell cancer that is:
- 12.1. Widely invasive
- 12.2. Poorly differentiated
- 12.3. Tumours greater than 2 cm
- 12.4. Diffuse sclerosing variants

#### Date of first enrolment

16/05/2012

#### Date of final enrolment

# Locations

## Countries of recruitment

United Kingdom

England

Study participating centre
Cancer Research UK & UCL Cancer Trials Centre
London
United Kingdom
W1T 4TJ

# Sponsor information

## Organisation

University College London (UCL) (UK)

#### **ROR**

https://ror.org/02jx3x895

# Funder(s)

# Funder type

Charity

## **Funder Name**

Cancer Research UK (CRUK) (UK)

#### Alternative Name(s)

CR\_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

# **Funding Body Type**

Private sector organisation

## **Funding Body Subtype**

Other non-profit organizations

#### Location

**United Kingdom** 

# **Results and Publications**

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from IoN trial manager (ctc.ion@ucl.ac.uk).

The type of data that will be shared: this will be dependent on the request and the data that the patient has consented to

When the data will become available and for how long: to be confirmed

By what access criteria data will be shared including with whom: researchers who wish to access data should contact the CTC (email address above)

For what types of analyses, and by what mechanism: will be assessed on a case-by-case basis Whether consent from participants was obtained: consent was given to collect the data. Data cannot be shared if patients withdrew consent to data collection/use.

Comments on data anonymisation: data will be pseudonymised

Any ethical or legal restrictions: research for the data request should be ethically approved

## IPD sharing plan summary

Available on request

## **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient- facing?
Results article	Phase III primary endpoint: 5-year recurrence-free survival results	18/06 /2025	24/06 /2025	Yes	No
HRA research summary			28/06 /2023	No	No
Participant information sheet	Participant information sheet	11/11 /2025	11/11 /2025	No	Yes
Study website	Study website	11/11 /2025	11/11 /2025	No	Yes