

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

<b>Submission date</b> 11/01/2011	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 03/03/2011	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 24/06/2025	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## 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:

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### **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 follow-up 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 aggressive histological features (small foci of aggressive 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. N0
  - 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. N0
  - 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**

30/03/2020

## Locations

### Countries of recruitment

United Kingdom

England

### Study participating centre

Cancer Research UK & UCL Cancer Trials Centre

London

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## 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?
<a href="#">Results article</a>	Phase III primary endpoint: 5-year recurrence-free survival results	18/06/2025	24/06/2025	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes