

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

Submission date 11/01/2011	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 03/03/2011	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 22/11/2023	Condition category Cancer	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English Summary

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

Study website

<http://www.ctc.ucl.ac.uk/>

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

2011-000144-21

IRAS number

75777

ClinicalTrials.gov number

NCT01398085

Secondary identifying numbers

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 hypothesis

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Condition

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 measure

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

Secondary outcome measures

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.

Overall study start date

16/05/2012

Overall study end date

31/03/2031

Eligibility

Participant 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

Age group

Adult

Lower age limit

16 Years

Sex

Both

Target number of participants

570

Total final enrolment

504

Participant 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

Recruitment start date

16/05/2012

Recruitment end date

30/03/2020

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Cancer Research UK & UCL Cancer Trials Centre

London

United Kingdom

W1T 4TJ

Sponsor information

Organisation

University College London (UCL) (UK)

Sponsor details

1st Floor Maple House

149 Tottenham Court Road

London

England

United Kingdom

W1T7DN

Sponsor type

University/education

Website

<http://www.ucl.ac.uk/joint-rd-unit/>

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, CRUK

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Results and Publications

Publication and dissemination plan

The final analysis is planned to be carried out in December 2023. Planned publication in a high-impact peer-reviewed journal.

Intention to publish date**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?
HRA research summary			28/06/2023	No	No