

Real time ultrasound elastography in the investig

Submission date 28/01/2015	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 28/01/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 17/10/2024	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

<http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-a-new-way-of-testing-thyroid-nodules-to-see-if-they-are-cancerous-or-not-elation>

Study website

<https://www.birmingham.ac.uk/elation>

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

142485

ClinicalTrials.gov number

Secondary identifying numbers

CPMS 17373, IRAS 142485

Study information

Scientific Title

The efficacy and cost effectiveness of real time ultrasound elastography in the investigation of thyroid nodules and the diagnosis of thyroid cancer

Acronym

ElaTION

Study objectives

The aim of this study is to compare the use of real time elastography (RTE) in conjunction with ultrasound to guide fine needle aspiration cytology FNAC (the intervention) with conventional ultrasound-only guided FNAC (current practice-comparator).

Ethics approval required

Old ethics approval format

Ethics approval(s)

NREC Committee South Central- Berkshire, 10/10/2014, ref: 14/SC/1206

Study design

Randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied

Topic: Cancer, Ear, nose and throat; Subtopic: Head and Neck Cancer, Ear (all Subtopics); Disease: Endocrine, Head and Neck

Interventions

Intervention arm- Real-time ultrasound elastography – guided FNAC. RTE is a technology that can be added at the same time as the routine ultrasound examination, and may help differentiate benign from malignant nodules based on the compression characteristics of the two.; Follow Up Length: 12 month(s)

Intervention Type

Procedure/Surgery

Primary outcome measure

Primary outcome measure as of 14/02/2017:

The proportion of patients who have a non-diagnostic (Thy1) cytology result following the first FNAC.

Original primary outcome measure:

The rate of benign histology result following thyroid surgery, compared between the RTE-FNAC arm and the conventional US-FNAC arm.

Secondary outcome measures

Secondary outcome measures as of 14/02/2017:

1. Number of FNACs required to obtain definitive diagnosis
2. Time from first FNAC to obtaining a definitive diagnosis
3. The proportion of patients with benign histology results following thyroidectomy
4. Proportion of patients who have thyroidectomy
5. Accuracy of a cytology results for first FNAC and repeated FNAC in relation to overall definitive diagnosis;
6. Accuracy of an imaging assessment on ultrasound (with or without RTE) alone diagnostic protocol in relation to overall definitive diagnosis
7. Patient reported outcome measures of depression and anxiety, pain, and quality of life: the Hospital Anxiety and Depression rating scale (HADS), Visual Analogue Pain Score (VAPS) and EQ-5D quality of life score
8. Radiologist report of whether RTE had contributed to the radiologist's decisions, how easy they found using RTE, and whether they found it helpful above using US-alone in predicting malignancy
9. Complication rate from any thyroidectomy at 30-days and 6-months post-surgery – to include haematoma and temporary hypocalcaemia rate at 30 days and vocal cord palsy and permanent hypocalcaemia at 6 months post-operative
10. Resource usage for consultant time and diagnostic testing procedures and subsequent management including consultations and surgical treatments

Original secondary outcome measures:

1. Overall number of FNAC's Required and time to obtain a definitive diagnosis in each arm
2. Non-diagnostic cytology (Thy1) rate for the first FNAC undertaken in each patient
3. Resource use for consultation time and diagnostic testing procedures and quality of life (EQ-5D)
4. Predictive value of a benign (Thy2) cytology results for first FNAC and repeated FNAC in relation to overall definitive diagnosis for RTE-FNAC and conventional US-FNAC
5. Patients reported anxiety immediately before and after US FNAC, immediately before each consultation for results of US FNA or surgery and at 6 and 12 months from initial US FNAC
6. Radiologist survey-completed by Radiologists at the end of the procedure to identify whether radiologists found US or RTE had contributed to their decision, ease of use, and their prediction of malignancy of the nodule using RTE or US features alone

7. Agreement rates for RTE between local operator and RTE or US features alone
8. Patient reported pain (by Visual analogue score) at procedure
9. Complication rate from any thyroidectomy- haematoma rate, vocal cord palsy at 6 months, permanent hypocalcaemia rate at 6 months
10. Cost-benefit analysis

Overall study start date

20/11/2014

Completion date

30/09/2022

Eligibility

Key inclusion criteria

1. Patients with single or multiple thyroid nodules whether solid, cystic or mixed, undergoing investigation who have not undergone previous FNAC within the last 6 months
2. Aged 18 years or over
3. Patient able and willing to give written informed consent

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned Sample Size: 968; UK Sample Size: 968

Total final enrolment

982

Key exclusion criteria

1. Patients who have undergone previous thyroid FNAC in the last 6 months.
2. Patients with a bleeding diathesis that precludes FNAC
3. Patients with a needle phobia.
4. Pregnant patients
5. Patients with purely cystic nodules or with recent haemorrhage, with no solid component

Date of first enrolment

27/02/2015

Date of final enrolment

30/09/2018

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Clinical Trials Unit (University of Birmingham)

Edgbaston

Birmingham

United Kingdom

B15 2TT

Sponsor information

Organisation

University of Birmingham

Sponsor details

Institute for Cancer Studies

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England

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Sponsor type

University/education

ROR

<https://ror.org/03angcq70>

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

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

30/03/2021

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	Evaluation of US elastography	18/11/2016	09/01/2023	No	No
HRA research summary			28/06/2023	No	No
Results article		01/08/2024	10/09/2024	Yes	No
Results article		15/10/2024	17/10/2024	Yes	No