ISRCTN18261857 https://doi.org/10.1186/ISRCTN18261857

Real time ultrasound elastography in the investig

Submission date	Recruitment status	[X] Prospectively registered
28/01/2015	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
28/01/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
17/10/2024	Cancer	

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

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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
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B15 2TT

Sponsor information

Organisation
University of Birmingham

Sponsor details
Institute for Cancer Studies
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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	version 5.0	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	Evaluation of US elastography	15/10/2024	17/10/2024	Yes	No