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The use of local anaesthetic (Lignocaine) in fine needle biopsy of thyroid nodules

Submission date	Recruitment status	[ ] Prospectively registered
12/09/2003	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
12/09/2003	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
26/09/2016	Respiratory	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0254119962

Study information

Scientific Title
The use of local anaesthetic (Lignocaine) in fine needle biopsy of thyroid nodules

Study objectives
To determine whether the use of 2% Lignocaine is beneficial in terms of patient acceptability /comfort and ease of operator technique, when compared with placebo (0.9% saline).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval was received from the local medical ethics committee before trial recruitment began

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Not Specified

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

Health condition(s) or problem(s) studied
Respiratory: Pain

Interventions
Consenting patients will receive either 2% Lignocaine or placebo (0.9% saline). The preparation received will be distributed by a randomised numbered system dictated by the pharmacy department of the Ipswich Hospital. Thus both patient and investigator will be blinded. Between 0.5 and 1.0 ml will be infiltrated with a 30G insulin needle under the skin immediately overlying the thyroid nodule. A period of at least 10 min and less than 20 min will be allowed to be elapsed before performing the biopsy. This will be performed using a standard technique where at least six biopsies will be attempted using a 25G needle. Patients will be asked to rate the level of discomfort experienced on a scale from between 1 and 5. The operator will also be asked to subjectively assess the ease of the procedure and his/her impression of the level of patient discomfort, again this will be rated on a scale from 1-5. The final assessment relates to the success in obtaining adequate specimens for cytological examination.

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome measure
Pain reduction

Secondary outcome measures
Number of aspirations attainable (up to 5) and success in obtaining adequate samples.

Overall study start date
18/03/2003

Completion date
31/12/2007

Eligibility

Key inclusion criteria
All patients attending for fine needle aspiration of the thyroid gland to the Ipswich Hospital NHS Trust will be asked to participate.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
60 patients (30 in each group)

Key exclusion criteria
Patients who have had a previous fine needle aspiration biopsy.

Date of first enrolment
18/03/2003

Date of final enrolment
31/12/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Ipswich Hospital NHS Trust
Ipswich, Suffolk
United Kingdom
IP4 5PD

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
Ipswich Hospital NHS Trust (UK)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration