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

Protocol serial number

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

Study type(s)

Not Specified

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(s)

Pain reduction

Key secondary outcome(s))

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

Completion date

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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

United Kingdom

England

Study participating centre Ipswich Hospital NHS Trust

Ipswich, Suffolk United Kingdom IP4 5PD

Sponsor information

Organisation

Funder(s)

Funder type

Government

Funder Name

Ipswich Hospital NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet Participant information sheet 11/11/2025 11/11/2025 No Yes