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

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

**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

## Primary study design
Interventional

## Study design
Randomised controlled trial

## 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

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

### 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

Department of Health (UK)

# 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