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

	Recruitment status	<ul><li>Prospectively registered</li></ul>
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

#### Contact name

Dr G Rayman

#### Contact details

Ipswich Hospital NHS Trust
Heath Road
Ipswich, Suffolk
United Kingdom
IP4 5PD
+44 (0)1473 704 183
gerry.rayman@ipswichhospital.nhs.uk

# 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