ISRCTN48936612 https://doi.org/10.1186/ISRCTN48936612

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

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

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

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

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