

A randomised comparison of two different methods of intrabronchial lignocaine delivery during flexible bronchoscopy

Submission date 29/01/2010	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 16/03/2010	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 03/04/2013	Condition category Surgery	☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Study information

Scientific Title

A randomised, controlled, open label, prospective, single centre study to investigate the use of the ENK device when compared to the standard syringe administration of 2% lignocaine solution when performing diagnostic flexible bronchoscopy

Study objectives

There is no difference in efficacy of local anaesthetic administration between standard "spray as you go" technique or the use of the ENK device during flexible bronchoscopy.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Preston, Chorley and South Ribble Local Research Ethics Committee approved on the 22nd March 2004 (ref: 2003.10.ix)

Primary study design

Interventional

Study design

Randomised controlled open label prospective single centre study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Local anaesthetic delivery in bronchoscopy

Interventions

Administration of local anaesthetic via either the standard "spray as you go" technique or nebulised through the bronchoscope via the ENK device (which has been used to assist in awake intubations previously. The same local anaesthetic agent is used for all participants with the volume used titrated according to the clinician's assessment of requirement. All patients complete a questionnaire greater than 24 hours following the procedure (and return it in a pre-addressed and stamped envelope). No additional follow up is required.

Intervention Type

Procedure/Surgery

Phase

Not Applicable

Primary outcome(s)

Visual analogue scale assessments by doctor, nurse and patient regarding ease of procedure, extent of coughing and patient tolerance. Doctor and nurse questionnaires completed immediately following the procedure. Patient questionnaires completed more than 24 hours later (to ensure there is no lasting effect of any sedative medication used).

Key secondary outcome(s)

No secondary outcome measures

Completion date

27/09/2006

Eligibility**Key inclusion criteria**

All adult patients (either sex) attending Royal Preston Hospital for diagnostic flexible bronchoscopy

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

Patients undergoing interventional procedures (e.g. tracheobronchial stenting, transbronchial biopsy or intraluminal palliative therapies)

Date of first enrolment

05/05/2004

Date of final enrolment

27/09/2006

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

1 Werneth Close

Preston

United Kingdom

PR19TS

Sponsor information**Organisation**

Lancashire Teaching Hospitals NHS Trust (UK)

ROR

<https://ror.org/02j7n9748>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Lancashire Teaching Hospitals NHS Trust (UK) - Research and Development Directorate (ref: JDM /MJ)

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?
Results article	results	01/04/2011		Yes	No