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		
		[X] 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

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N/A

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)

Study design

Randomised controlled open label prospective single centre study

Primary study design Interventional

Secondary study design Randomised controlled trial

Study setting(s) Hospital

Study type(s) Treatment

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

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 anaesthesic 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 preaddressed and stamped envelope). No additional follow up is required.

Intervention Type

Procedure/Surgery

Phase

Not Applicable

Primary outcome measure

Visual analoque 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).

Secondary outcome measures

No secondary outcome measures

Overall study start date 05/05/2004

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

Age group Adult

Sex Both

Target number of participants 100

Key exclusion criteria

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

Date of first enrolment 05/05/2004

Date of final enrolment 27/09/2006

Locations

Countries of recruitment England

United Kingdom

Study participating centre 1 Werneth Close Preston United Kingdom PR19TS

Sponsor information

Organisation Lancashire Teaching Hospitals NHS Trust (UK)

Sponsor details Sharoe Green Lane Preston England United Kingdom PR29HT

Sponsor type Hospital/treatment centre

Website http://www.lancsteachinghospitals.nhs.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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Results article</u>	results	01/04/2011		Yes	No