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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 [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 16/03/2010	**Overall study status** Completed	
Last Edited 03/04/2013	**Condition category** Surgery	

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
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

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 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 pre-addressed and stamped envelope). No additional follow up is required.

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome(s)
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).

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 intrluminal 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