ISRCTN77331907 https://doi.org/10.1186/ISRCTN77331907

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

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 pre-addressed 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?
Results article	results	01/04/2011		Yes	No