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Beta Agonist Lung Injury TrIal (BALTI) Prevention Study

Submission date 02/01/2008	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 29/02/2008	**Overall study status** Completed	
Last Edited 09/01/2014	**Condition category** Cancer	

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
Beta Agonist Lung Injury TrIal (BALTI) Prevention Study: a multicentre, double-blind, randomised, placebo-controlled trial

Acronym
BALTI Prevention Study

Study objectives
Those recruited will be suffering from oesophageal cancer. They will be undergoing oesophagectomy and the surgical procedure will involve collapsing one lung. There is a high post-operative risk of acute lung injury.

Hypothesis:
Inhaled salmeterol prior to elective oesophagectomy will reduce the incidence of early acute lung injury.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Birmingham Ethics Committee approved on the 15th November 2007 (ref: 07/H1207/233)

Study design
Multicentre double-blind randomised placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

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
Oesophageal cancer

Interventions
Inhaled salmeterol (100 µg) via spacer immediately prior to surgery, and then afterwards twice daily for 72 hours, versus placebo inhaler. If the patient is ventilated the drug will be given through the inspiratory limb of the ventilator.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Salmeterol

Primary outcome measure
The development of clinically significant acute lung injury within 72 hours of oesophagectomy.

Secondary outcome measures
1. Global severity of illness at admission to Intensive Therapy Unit (ITU): Acute Physiology And Chronic Health Evaluation (APACHE II)
2. Severity of respiratory illness (partial pressure of oxygen in arterial blood [PaO2]:Fraction of inspired Oxygen [FiO2] ratio) daily for duration of intensive care unit (ITU)/high dependency unit (HDU) stay
3. Development of acute lung injury/acute respiratory distress syndrome (ARDS) at day 0 - 28
4. Ventilator free days
5. Organ failure free days
6. 28 and 90 day survival
7. Health related quality of life (EQ-5D) at baseline and at 28 and 90 days

Overall study start date
01/03/2008

Completion date
01/03/2011

Eligibility

Key inclusion criteria
1. Planned elective transthoracic oesophagectomy patients
2. Aged greater than 18 years
3. Male and female
4. Able to provide informed consent
5. Able to use a spacer device to deliver the drug

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex

Both

Target number of participants
216 (increased to 360 as of 18/06/2009)

Key exclusion criteria
1. Pregnancy
2. Current treatment with long acting beta agonist
3. Allergy to excipients in salmeterol
4. Current treatment with non-cardioselective beta-blockers
5. Treatment with investigational medicinal product (IMP) in the last 30 days

Date of first enrolment
01/03/2008

Date of final enrolment
01/03/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Associate Clinical Professor
Birmingham
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B9 5SS

Sponsor information

Organisation
Birmingham Heartlands Hospital (UK)

Sponsor details
c/o Dr Liz Adey
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01bd5gh54

Funder(s)

Funder type
Government

Funder Name
Department of Health (UK) - the Research Capacity Development (RCD) Programme (ref: PAS/02/06/RDA/010)

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?
Protocol article	protocol	15/03/2011		Yes	No
Results article	results	15/03/2014		Yes	No