Beta Agonist Lung Injury Trial (BALTI) Prevention Study

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

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

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 μ g) 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 United Kingdom B9 5SS

Sponsor information

Organisation

Birmingham Heartlands Hospital (UK)

Sponsor details

c/o Dr Liz Adey Bordesley Green East Birmingham England United Kingdom B9 5SS Liz.Adey@heartofengland.nhs.uk

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