# VItamiN D replacement to prevent Acute Lung injury following OesophagectOmy (VINDALOO-2)

Submission date Recruitment status [X] Prospectively registered 03/11/2011 No longer recruiting [X] Protocol Statistical analysis plan Registration date Overall study status 21/12/2011 Completed [X] Results [ ] Individual participant data Last Edited Condition category 29/10/2018 Cancer

#### Plain English summary of protocol

Not provided at time of registration

#### Contact information

#### Type(s)

Scientific

#### Contact name

Dr David Thickett

#### Contact details

University of Birmingham Birmingham United Kingdom B15 2TT +44 (0)121 472 1311 (ext: 8289) d.thickett@bham.ac.uk

#### Additional identifiers

**EudraCT/CTIS** number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

version 1 3-3-2011

## Study information

#### Scientific Title

Vitamin D replacement to prevent acute lung injury following oesophagectomy - a randomised placebo controlled trial

#### Acronym

VINDALOO-2

#### **Study objectives**

This is a randomised double-blind placebo-controlled study to test the safety and efficacy of rapid vitamin D replacement upon extravascular lung water and markers of alveolar/systemic inflammation in patients undergoing oesophagectomy.

The pilot study was registered in September 2011: www.controlled-trials.com/ISRCTN66719785

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Not provided at time of registration

#### Study design

Randomised placebo-controlled phase II 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

Oesphageal cancer, acute lung injury

#### **Interventions**

Oral vitamin D liquid (100,000 IU) versus identical placebo

#### Intervention Type

Supplement

#### Primary outcome measure

Extravascular lung water index (EVLWI) at the end of oesophagectomy

#### Secondary outcome measures

Clinical markers indicative of lung injury:

- 1. P:F ratio
- 2. Oxygenation index
- 3. Development of lung injury / ARDS day 0-28
- 4. Duration of ventilation and organ failure, survival
- 5. Safety and tolerability of vitamin D supplementation
- 6. Plasma indices of endothelial and alveolar epithelial function/injury
- 7. Plasma inflammatory response
- 8. Plasma LL-37 levels
- 9. Plasma vitamin D status (25D3, 1,25D3 and VDBP)
- 10. EVLWI post-operative day 1

#### Overall study start date

01/04/2012

#### Completion date

01/04/2014

# **Eligibility**

#### Key inclusion criteria

- 1. Planned transthoracic oesophagectomy for oesophageal carcinoma at a participating centre
- 2. Aged over 18 years on day of first dose of investigational medicinal product (IMP)
- 3. Ability to give written informed consent to participate in the study

#### Participant type(s)

Patient

#### Age group

Adult

#### Lower age limit

18 Years

#### Sex

Both

#### Target number of participants

80

#### Key exclusion criteria

- 1. Known intolerance of vitamin D
- 2. Known sarcoidosis, hyperparathyroidism, or nephrolithiasis
- 3. Taking more than 1000iu/day vitamin D supplementation in the month preceding enrolment
- 4. Baseline serum corrected calcium >2.65 mmol/L
- 5. Undergoing haemodialysis

- 6. Pregnant or breastfeeding
- 7. Taking cardiac glycoside, carbamazepine, phenobarbital, phenytoin, primidone or long-term immunosuppressant therapy
- 8. Taking oral preparation containing > 10 micrograms vitamin D/day up to 2 months before first dose of IMP
- 9. Diagnosis of COPD with an FEV1 less than 50% predicted or resting oxygen saturations of less 92%

#### Date of first enrolment

01/04/2012

#### Date of final enrolment

01/04/2014

#### Locations

#### Countries of recruitment

England

United Kingdom

# Study participating centre University of Birmingham

Birmingham United Kingdom B15 2TT

# Sponsor information

#### Organisation

University of Birmingham (UK)

#### Sponsor details

Edgbaston
Birmingham
England
United Kingdom
B15 2TT
+44 (0)121 414 3344
b.a.laverty@bham.ac.uk

#### Sponsor type

University/education

#### Website

http://www.birmingham.ac.uk/

#### ROR

https://ror.org/03angcq70

# Funder(s)

#### Funder type

Research council

#### Funder Name

Medical Research Council UK (MRC) ref: G1100196

### **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	17/04/2013		Yes	No
Results article	results	01/12/2018		Yes	No