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

Submission date 03/11/2011	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 21/12/2011	**Overall study status** Completed	
Last Edited 29/10/2018	**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
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
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B15 2TT

Sponsor information

Organisation
University of Birmingham (UK)

Sponsor details
Edgbaston
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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