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A dosing study to optimise vitamin D levels prior to oesophagectomy

Submission date	**Recruitment status**	[X] Prospectively registered
19/08/2011	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
26/09/2011	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
29/01/2018	Cancer	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Oesophagectomy is the surgical removal of the oesophagus (food pipe), for example to remove oesophageal cancer. Sometimes following oesophagectomy the lungs become inflamed - a condition that is called acute lung injury. This happens about 28% of the time following oesophagectomy and the causes for it are poorly understood. The condition can range in severity from causing mild breathlessness to more severe breathlessness that can require assistance from a ventilator (breathing machine) to help with breathing in intensive care. We believe that people who are severely vitamin D deficient may be more at risk of acute lung injury following the operation than those who are not. We have previously done research which suggests that people who need an oesophagectomy are usually vitamin D deficient with about half being very deficient. We have evidence from our previous studies that those with the lowest levels of vitamin D may be at increased risk of inflammation and acute lung injury. The aim of this study is to determine whether we can restore vitamin D levels rapidly in the week or so prior to surgery using a single dose of liquid vitamin D taken by mouth.

Who can participate?
Patients aged over 16 undergoing oesophagectomy for oesophageal cancer.

What does the study involve?
Participants are given one of three doses of liquid vitamin D about 7 days before their oesophagectomy. We then measure their blood vitamin D levels after 7, 10 and 14 days.

What are the possible benefits and risks of participating?
Not provided at time of registration.

Where is the study run from?
University of Birmingham (UK).

When is the study starting and how long is it expected to run for?
November 2011 to June 2012.

Who is funding the study?
Medical Research Council (UK).

Who is the main contact?
Dr David Thickett
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
Version 1.0 19-08-2011

Study information

Scientific Title
A phase II open label dosing study to optimise vitamin D levels prior to oesophagectomy

Acronym
VINDALOO

Study objectives
Developing vitamin D therapy to prevent acute respiratory distress syndrome following oesophagectomy. To study the optimal dose of vitamin D to be give preoperatively in patients undergoing oesophagectomy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval pending as of 22/08/2011

Primary study design
Interventional

Study design
Open-labelled sequential dose-escalation study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Oesophageal cancer/acute lung injury/oesophagecetomy

Interventions
Patients will be given a single dose of oral Vigantol® liquid approximately 7 days preoperatively.

Doses will be 100,000 units, 200,000 units or 300,000 units of vitamin D.

Intervention Type
Supplement

Phase
Phase II

Drug/device/biological/vaccine name(s)
Vitamin D (Vigantol®)

Primary outcome(s)
The dose of Vigantol® that successfully increases serum vitamin D levels above 75 nmol/l in all cases

Key secondary outcome(s)
1. Safety and tolerability data - blood biochemistry, medication related side effects
2. Plasma 25D3 levels at 7, 10 and 14 days post dose
3. Plasma LL-37 (a downstream vitamin D target) at baseline and on the day of operation
4. Change in Plasma 1, 25 D3 (the biologically active hormone) from baseline on the day of operation

Completion date
01/06/2012

Eligibility

Key inclusion criteria
1. Planned transthoracic oesophagectomy for oesophageal carcinoma at a participating centre
2. Aged over 16 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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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 chronic obstructive pulmonary disease (COPD) with an forced expiratory volume in one second (FEV1) less than 50% predicted or resting oxygen saturations of less 92%

Date of first enrolment
01/11/2011

Date of final enrolment
01/06/2012

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Birmingham
Birmingham
United Kingdom
B15 2TT

Sponsor information

Organisation

University of Birmingham (UK)

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK) (ref: G1100196)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration