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Does taking vitamin D3 before esophageal surgery reduce the risk of lung complications?

Submission date
16/12/2024

Recruitment status
No longer recruiting

Registration date
31/01/2025

Overall study status
Completed

Last Edited
29/01/2025

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Oesophageal cancer is a major cause of cancer-related deaths worldwide. The main treatment is esophagectomy, a complex surgery with high risks. Up to 40% of patients experience complications after surgery, especially lung issues like pneumonia and acute respiratory distress syndrome (ARDS). This study investigates whether taking a high dose of vitamin D3 before surgery can reduce the risk of these lung complications.

Who can participate?
Adults over 18 years old with oesophageal cancer scheduled for esophagectomy can participate in this study.

What does the study involve?
Participants are randomly assigned to receive either a single high dose of vitamin D3 or a placebo before their surgery. The study monitors their lung health and recovery after the operation.

What are the possible benefits and risks of participating?
The potential benefit is a reduced risk of lung complications after surgery. The risks are minimal since vitamin D3 is generally safe, but there may be some side effects from the high dose.

Where is the study run from?
University Hospital Bratislava (Slovakia)

When is the study starting and how long is it expected to run for?
September 2018 to June 2025

Who is funding the study?
The study is funded by the Slovak Society of Anesthesia & Intensive Care Medicine.

Who is the main contact?
Dr Katarina Tarabova, katarina.tarabova@ru.unb.sk

Contact information

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Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
No EC/193/2018

Study information

Scientific Title
The association between preoperative single high-dose vitamin D3 supplementation and ARDS (Acute respiratory distress syndrome) incidence in patients after esophageal resection for carcinoma- a randomised, placebo-controlled trial (ESOVID)

Acronym
ESOVID

Study objectives
The study aims to investigate whether preoperative supplementation with oral cholecalciferol would reduce the risk of ARDS development following oesophagectomy, as measured by the extravascular lung water index (EVLWI) and pulmonary vascular permeability index (PVPI).

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 26/09/2018, The Local Ethics Committee, University Hospital Bratislava (Ruzinovska 6, Bratislava, 82606, Slovakia; +421 248234793; okf@ru.unb.sk), ref: No EC/193/2018

Study design
Randomized double-blind placebo-controlled Phase II study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Esophageal cancer, acute respiratory distress syndrome

Interventions
Randomisation Process
- Randomisation Method: Patients were randomised using a dice. An even number assigned patients to the treatment group, while an odd number assigned them to the placebo group.

Study Arms

1. Treatment Group
- Number of Patients: 40
- Treatment:
- 3-5 days before surgery: 300,000 IU of vitamin D3 (15 ml)
- Day of Surgery: Standard surgical procedures
- Postoperative Days (POD) 1 to 6: Monitoring and evaluations
- Measurements:
- Calcium & 25-OH vitamin D plasma levels
- Extravascular Lung Water Index (EVLWI) & Pulmonary Vascular Permeability Index (PVPI) after

catheterisation and 1 hour postoperatively
- One-lung ventilation (OLV) duration
- Tidal volume during OLV
- Amount of intraoperative fluid administration
- Follow-Up:
- POD1: EVLWI & PVPI measurements
- POD1 to POD6: Sequential Organ Failure Assessment (SOFA) evaluation
- POD6: Calcium & 25-OH vitamin D plasma levels

2. Placebo Group
- Number of Patients: 40
- Treatment:
- 3-5 days before surgery: Medium-chain triglyceride (MCT) oil (15 ml)
- Day of Surgery: Standard surgical procedures
- Postoperative Days (POD) 1 to 6: Monitoring and evaluations
- Measurements:
- Calcium & 25-OH vitamin D plasma levels
- EVLWI & PVPI after catheterisation and 1 hour postoperatively
- OLV duration
- Tidal volume during OLV
- Amount of intraoperative fluid administration
- Follow-Up:
- POD1: EVLWI & PVPI measurements
- POD1 to POD6: SOFA evaluation
- POD6: Calcium & 25-OH vitamin D plasma levels

Summary
- Total Duration of Treatment: 3-5 days before surgery to POD6
- Follow-Up Duration: From the day of surgery to POD6
- Randomisation Details: Dice roll (even for treatment, odd for placebo)

Intervention Type
Supplement

Primary outcome(s)
1. Extravascular lung water index (EVLWI) and pulmonary vascular permeability index (PVPI) evaluation one hour postoperatively and on postoperative Day 1.
2. Acute respiratory distress syndrome incidence during the hospital stay.

Key secondary outcome(s))
1. Impact of cholecalciferol supplementation on vitamin D3 plasma levels at surgery day and postoperative day 6.
2. Effect of preoperative cholecalciferol supplementation on the need for mechanical ventilation and its duration of mechanical ventilation duration in patients with respiratory failure.
3. Effect of preoperative cholecalciferol supplementation on SOFA score.
4. Effect of preoperative cholecalciferol supplementation on the presence of respiratory complications.
5. Effect of preoperative cholecalciferol supplementation on length of ICU stay.
6. Effect of preoperative cholecalciferol supplementation on 30 and 90-day mortality.
7. Effect of preoperative cholecalciferol supplementation on 3-year survival.

Completion date
30/06/2025

Eligibility

Key inclusion criteria
1. Patients over 18 years old
2. Planned transthoracic oesophagectomy for oesophageal carcinoma
3. One-lung ventilation during operation
4. Ability to obtain written consent for participation in the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
84

Key exclusion criteria
1. Known intolerance to oral cholecalciferol
2. Inability to swallow
3. Known sarcoidosis, hyperparathyroidism, or nephrolithiasis
4. Serum calcium >2.65 mmol/l
5. Undergoing haemodialysis
6. Pregnant or breastfeeding
7. Diagnosis of chronic obstructive pulmonary disease (COPD) with a forced expiratory volume in one second (FEV1) less than 50% predicted or resting oxygen saturation of less than 92%
8. Oesophageal resection without the use of OLV
9. Failure to obtain informed consent

Date of first enrolment
01/01/2019

Date of final enrolment
30/06/2022

Locations

Countries of recruitment

Slovakia

Study participating centre
University Hospital Bratislava
Ruzinovska 6
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82606

Sponsor information

Organisation
University Hospital Bratislava

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Slovak Society of Anesthesia & Intensive Care Medicine

Funder Name
University Hospital Bratislava

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and analysed during the current study will be available upon request from Dr Katarina Tarabova, PhD., e-mail: katarina.tarabova@ru.unb.sk

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	in English in Slovak		29/01/2025	No	Yes

Participant information sheet	29/01/2025	No	Yes