A randomized controlled trial on the effect of beetroot juice on VO2max in patients undergoing a minimally invasive esophagectomy

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20212

Source
NTR

Brief title
BEET-MIE

Health condition

Esophageal cancer, esophagectomy, postoperative complications, cardiopulmonary complications, anastomic leakage, Quality of Life

Sponsors and support

Primary sponsor: Catharina Hospital Eindhoven
Source(s) of monetary or material Support: Stichting Catharina Onderzoeksfonds (Catharina Research Foundation) project number 2020-004

Intervention

Outcome measures

Primary outcome

- Predicted VO2max (ml/kg/min)

Secondary outcome

- All 30-day and in-hospital postoperative complications specifically:
> Cardiopulmonary complications
- Other PREPARE measurements, e.g.:
Maximum power output/wattage (Wmax)
> Predicted VO2peak (ml/kg/min)
> Maximum inspiratory pressure (MIP)
> Spirometry measurements (e.g. forced expiratory volume in 1 second; FEV1)
- Functional recovery, total length of hospital and ICU stay and readmission rate
- Quality of life (EuroQol EQ-5D-5L and EORTC QLQ-C30 validated questionnaires)

Study description

Background summary

BEET-MIE is a 2-arm RCT investigating the added effect of one consecutive week of beetrootjuice (BRJ) consumption in prehabilitated patients scheduled to undergo a minimally invasive esophagectomy for cancer. Primarily the impact on VO2max. Cardiopulmonary complications, functional recovery, surgical complications and quality of life amongst others are also carefully monitored.

Study objective

It has been reported that patients with lower VO2max and VO2peak (the peak oxygen uptake during incremental exercise) values, have a significantly higher risk of cardiopulmonary complications (CPC) following an esophagectomy, while consumption of beetroot juice has been shown in multiple studies to improve exercise performance and oxygen metabolism (including VO2max and VO2peak) in both young, healthy individuals as well as the elderly suffering from cardiovascular disease and COPD.

Study design

- VO2max and other PREPARE measurements: 1 week preoperatively and at admission on the day before surgery
- Functional recovery: during admission.
- Cardiopulmonary complications: within 30 days after surgery.
- Anastomotic leakage: within 30 days after surgery by clinical/radiological signs or confirmed by reoperation
- All other (surgical) complications: within 30 days after surgery
- Quality of life: baseline, 1 week preoperatively, at admission on the day before surgery, 1 week, 3 weeks, and 6 weeks postoperatively

Intervention

Nitrate-rich Beet It Sport shot (70cc) versus nitrate-depleted Beet It Sport shot (placebo, 70cc). Depending on randomization patients will be take 1 bottle once daily for seven consecutive days directly before surgery.
The aforementioned PREPARE program is a personalized, home-based prehabilitation program for all esophageal cancer patients scheduled to undergo an elective esophagectomy. Nutritional status, physical capacity and mental wellbeing of patients is optimized in collaboration with and under supervision of a multidisciplinary team from the hospital. The PREPARE program has already been fully implemented since 2018.

Contacts

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Eligibility criteria

Inclusion criteria

- Prehabilitated patients undergoing an elective minimally invasive Ivor-Lewis esophagectomy with intrathoracic anastomosis
- Written informed consent
- Age >18 years

Exclusion criteria

Allergy to beets/BRJ
Inability to tolerate oral intake, e.g. swallowing disorder
Inability to follow the PREPARE program
Inability to provide written consent

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2020
Enrollment:	100
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 49240
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL8560
CCMO	NL72405.100.20
OMON	NL-OMON49240

Study results