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

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The primary aim of this study is to investigate the added effect of one consecutive week of BRJ consumption on VO2max in prehabilitated patients scheduled to undergo a minimally invasive esophagectomy for cancer.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Interventional

Summary

ID

NL-OMON49240

Source
ToetsingOnline

Brief title
BEET-MIE

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC

Synonym
Esophagectomy

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis

Source(s) of monetary or material Support: Medtronic;Catharina onderzoeksfonds

Intervention

Keyword: Beetroot juice, Esophageal cancer, Esophagectomy, Prehabilitation

Outcome measures

Primary outcome

Improvement of VO2max (ml/kg/min) is the primary outcome parameter.

Secondary outcome

All 30-day and in-hospital postoperative complications specifically:

o Cardiac complications

o Pulmonary complications

Quality of life (EuroQol EQ-5D-5L and EORTC QLQ-C30 validated questionnaires)

Functional recovery

PREPARE measurements, eg.

o Maximum inspiratory pressure (MIP)

o Forced expiratory volume in 1 second (FEV1)

o Total length of hospital and Intensive Care Unit (re)admission

Study description

Background summary

The cornerstone for curative treatment of esophageal cancer is an esophagectomy and with the introduction of neoadjuvant chemoradiotherapy, the survival rate for patients undergoing surgery has significantly improved over the past decades. However, an esophagectomy is a technically challenging procedure that requires sufficient amount of surgeon volume to progress through the learning curve, in addition to the intensive treatment associated with a high postoperative morbidity. Despite improvements in perioperative care, such as introduction of enhanced recovery after surgery programs (ERAS) and minimally

invasive surgery, postoperative morbidity following an esophagectomy remains substantial. More specifically, the cardiopulmonary complication rate remains around 52% (own data).
In this light, prehabilitation has gained increasing attention. Prehabilitation consists of various interventions to optimize the patient*s preoperative physical and mental state. Improvement of a patient*s fitness should lead to a better functional capacity that allows patients to better withstand the postoperative stress response by increasing the maximum oxygen uptake (VO2max). In major abdominal surgery, multiple studies have indicated that prehabilitation not only improves preoperative functional capacity but that it also has a beneficial effect on short-term outcomes. In patients undergoing an esophagectomy, evidence on the effectivity of prehabilitation is scarce, however, 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.
In sports medicine, multiple studies have shown that BRJ supplementation increases VO2max and thereby improves exercise performance and oxygen metabolism in both young, healthy individuals as well as the elderly suffering from cardiovascular disease and COPD. BRJ supplementation increases time to exhaustion during high-intensity exercise and reduces oxygen consumption (VO2) during submaximal exercise via release of Nitric Oxide (NO). BRJ contains an abundant amount of nitrate and it is thought that VO2max may be increased via NO-mediated changes in local perfusion in skeletal muscle and possible effects on cardiac output. However, the exact mechanisms remain unclear and most of these studies are limited by a small study population and effect size. Positive effects of BRJ supplementation are mostly described when BRJ is taken at least one consecutive week of daily dosing rather than one single dose.

Study objective

The primary aim of this study is to investigate the added effect of one consecutive week of BRJ consumption on VO2max in prehabilitated patients scheduled to undergo a minimally invasive esophagectomy for cancer.

Study design

This study will be a single center, double-blind, randomized, placebo-controlled trial. The Catharina Hospital Eindhoven, the Netherlands - which is a tertiary referral center for esophageal cancer - is the only Dutch hospital with a prehabilitation program (PREPARE) installed for patients scheduled to undergo an esophagectomy.

Intervention

The intervention group will receive the Beet It Sport Shot - manufactured by James White Drinks (Ipswich, UK) - containing 400 mg (~6.5 mmol) nitrate per

bottle of 70 millilitres, to take once daily for seven days prior to surgery. The control group (placebo) will receive an identical (blinded) bottle of the Beet It Sport Shot of 70 millilitres in which the nitrate has been removed by the manufacturer, to also take once daily for seven days prior to surgery.

Study burden and risks

BRJ consumption has not yet been investigated in this population. However, previous and similarly designed trials in various study populations did not report serious adverse events or major health consequences from BRJ consumption and showed a good tolerance of the supplementation regimen. BRJ supplementation is commercially available and approved for consumption. Thus, we expect no additional events or complications caused by BRJ consumption in this trial compared to previous trials. Measurements will be part of the standard clinical care pathway installed at the hospital

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

All prehabilitated patients with esophageal cancer or esophagogastric junction cancer undergoing an elective minimally invasive esophagectomy with with intrathoracic anastomosis (Ivor-Lewis)
Ability to provide verbal and written informed consent
Age >=18 years

Exclusion criteria

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

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-10-2020
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	15-04-2020
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	14-07-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	28-12-2022
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	22-10-2024
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 20212
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL72405.100.20