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

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Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20212

Bron
NTR

Verkorte titel
BEET-MIE

Aandoening

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

Ondersteuning

Primaire sponsor: Catharina Hospital Eindhoven
Overige ondersteuning: Stichting Catharina Onderzoeksfonds (Catharina Research Foundation) project number 2020-004

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- Predicted VO2max (ml/kg/min)

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

- 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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Catharina Ziekenhuis Eindhoven
Thijs Janssen

(+31)040 - 239 7169 or (+31)040 - 239 6350

Wetenschappelijk

Catharina Ziekenhuis Eindhoven
Thijs Janssen

(+31)040 - 239 7169 or (+31)040 - 239 6350

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-10-2020
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 49240
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten