

Potassium values before and after PEG-asc for colonoscopy

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The use of PEG-asc could contribute a significant decrease in potassium values a potentially cause serious clinical adverse events.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON21540

Bron

NTR

Aandoening

Prevalence of hypokalemia, mean potassium difference before/after bowel cleansing, age, gender, comorbidity, indication, and symptom related parameters.

Ondersteuning

Primaire sponsor: Zuyderland Medical Center, Heerlen

Division of Gastroenterology and Hepatology, Department of Internal Medicine

Overige ondersteuning: Zuyderland Medical Center, Heerlen

Division of Gastroenterology and Hepatology, Department of Internal Medicine

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Primary aim. The primary study endpoint will be the detection of hypokalaemia, which is defined as a potassium value < 3.5 mmol/L at t0 and t1.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Patients undergoing colonoscopy could have an (unknown) risk of hypokalaemia due to bowel cleansing and other risk factors, such as comorbidity and age. Patients with pre-existing hypokalaemia are at risk for severe hypokalaemia. By performing this study, we want to define risk factors and provide a new protocol for bowel cleansing in our hospital.

Objective: All patients undergoing colonoscopy.

Study design: Population-based, observational study

Study population: All patients undergoing colonoscopy ≥ 18 years old.

Main study parameters/endpoints: Prevalence of hypokalaemia, mean potassium difference before/after bowel cleansing, age, gender, comorbidity, indication, and symptom related parameters.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: To minimize the risks for patients undergoing colonoscopy we will check potassium values as standard care. The existing protocol will be expanded for all patients. Every ambulatory patient visits the screening nurse for information and risk stratification. One blood sample is obtained approximately 1 week before start of bowel cleansing and one blood sample via intravenous needle (already needed for infusion of analgesics and sedation) on the day of colonoscopy.

Doel van het onderzoek

The use of PEG-asc could contribute a significant decrease in potassium values a potentially cause serious clinical adverse events.

Onderzoeksopzet

Analyses will be performed after colonoscopy

Onderzoeksproduct en/of interventie

1. Clinical data registration

2. Evaluation of potassium measurements in patients before and after bowel preparation (standard health care)

Contactpersonen

Publiek

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Wetenschappelijk

Zuyderland Medisch Centrum locatie Heerlen - poli Maag-darm-leverziekten

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- All patients undergoing colonoscopy in Zuyderland Medical Center
- Age ≥ 18 years

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential subject who meets any of the following criteria will be excluded from participation in this study:

- All patients < 18 years
- Emergency colonoscopy

Onderzoeksopzet

Opzet

Type: Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel: Anders
Controle: N.v.t. / onbekend

Deelname

Nederland
Status: Werving gestart
(Verwachte) startdatum: 04-01-2016
Aantal proefpersonen: 2000
Type: Verwachte startdatum

Ethische beoordeling

Positief advies
Datum: 08-04-2016
Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5416
NTR-old	NTR5744
Ander register	METC Zuyderland - Zuyd : 15-N-146

Resultaten

Samenvatting resultaten

in progress