Potassium values before and after PEG-asc for colonoscopy

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21540

Source
NTR

Health condition

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

Sponsors and support

Primary sponsor: Zuyderland Medical Center, Heerlen
Division of Gastroenterology and Hepatology, Department of Internal Medicine
Source(s) of monetary or material Support: Zuyderland Medical Center, Heerlen
Division of Gastroenterology and Hepatology, Department of Internal Medicine

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

Secondary aim: to determine risk factors for the development of hypokalemia.

Study description

Background summary

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.

Study objective

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

Study design

Analyses will be performed after colonoscopy

Intervention

1. Clinical data registration

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

Contacts

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Eligibility criteria

Inclusion criteria

• All patients undergoing colonoscopy in Zuyderland Medical Center

• Age ≥18 years

Exclusion criteria

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

• All patients < 18 years

• Emergency colonoscopy

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-01-2016
Enrollment:	2000
Type:	Anticipated

Ethics review

Positive opinion

Date:	08-04-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

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

Study results

Summary results
in progress