

# FREQUENCY AND SEVERITY OF HYPONATREMIA CAUSED BY PICOPREP BOWEL PREPARATION

Published: 02-08-2017

Last updated: 12-04-2024

Study the frequency and severity of hyponatremia caused by Picoprep bowel preparation.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Gastrointestinal signs and symptoms
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON45401

### Source

ToetsingOnline

### Brief title

Bowelpreparation induced hyponatremia

### Condition

- Gastrointestinal signs and symptoms

### Synonym

hyponatremia, low serum level of sodium

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Ikazia Ziekenhuis

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Adverse events, Bowel preparation, Hyponatremia

## Outcome measures

### Primary outcome

- Presence of hyponatremia, defined as a serum sodium of  $<135$ .
- Presence of severe hyponatremia, either being a serum concentration  $<125$  of in case of severe symptoms (seizure, coma)
- Morbidity (altered mental status, seizures, headache)

### Secondary outcome

N.a.

## Study description

### Background summary

Colonoscopy is the current standard method for imaging the mucosa of the entire colon. The diagnostic accuracy and therapeutic safety of colonoscopy depends, in part, on the quality of the colonic cleansing or preparation. Current European guidelines recommend a (split) regimen of a polyethylene glycol (PEG) solution or 2 liter PEG plus ascorbate or sodium picosulphate plus magnesium citrate. PEG stays intraluminal and thus it is generally not expected that it influences serum electrolytes significantly. Sodium picosulphate plus magnesium citrate has both stimulative (picosulphate) and osmotic (magnesium citrate) effects and thus can alter serum electrolytes and minerals. Despite its better tolerance compared to PEG solution, bowel preparation with sodium picosulphate plus magnesium citrate is associated with developing a hyponatremia in 1%-20% of patients in clinical trials depending on its definition. Possible contributing factors are a rise in anti-diuretic hormone, increased intake of fluid and clearance of free water. Symptoms of hyponatremia depend on its severity and the rapidity of its development. Nausea, malaise, headache, lethargy, seizures, rhabdomyolysis and even a respiratory arrest may develop in case of acute hyponatremia. Recently two patients developed severe hyponatremia (seizures, coma) after they had taken Picoprep bowel preparation at our department. Patients often complain about headaches after taking bowel

preparation which could also be caused by a decrease in the serum sodium level.

### **Study objective**

Study the frequency and severity of hyponatremia caused by Picoprep bowel preparation.

### **Study design**

Prospective cohort study. are eligible for participation in this study.

### **Study burden and risks**

The burden associated with participation is limited. This includes two times blood sampling and for some participants (with a sodium  $<130$ ) once urine analysis.

There are no risks associated with participation.

## **Contacts**

### **Public**

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### **Scientific**

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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 adult patients using Picoprep bowel preparation scheduled for an outpatient based colonoscopy

### Exclusion criteria

Sodium level at baseline <130 mmol/L

Age <18 years

Inability to give written informed consent

## Study design

### Design

**Study type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

### Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-05-2017

Enrollment: 200

Type: Anticipated

## Ethics review

Approved WMO

Date:	02-08-2017
Application type:	First submission
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

No registrations found.

### In other registers

Register	ID
CCMO	NL60483.101.17