

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jun 2026

Comparison of low dose PEG (polyethylene glycol) and low dose PEG with Sena grafin regarding bowel preparation quality in patients with chronic kidney disease

Protocol summary

Study aim

Comparison of low dose PEG (polyethylene glycol) and low dose PEG with Sena grafin in the regarding bowel preparation quality in patients with chronic kidney disease

Design

Two arm parallel group, three-blind, randomized by permutation block method, phase 3, design of 122 patients

Settings and conduct

122 patients admitted to Imam Hossein Hospital who were candidates for colonoscopy for any reason and at the same time had chronic kidney disease (during the last three months or more GFR <60 ml / min) were included in the study. The patient and the staff and the doctor performing the colonoscopy did not know the type of solution received. The containing boxes was were the same and without label.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. age of more than 18 years, 2. presence of CKD in patients who are candidates for colonoscopy (GFR < 60 based on MDRD formula).
Exclusion criteria: 1. CKD patients needing dialysis or CKD patients with a GFR of less than 15, 2. Patients who experienced acute kidney injury (AKI) imposed on their CKD condition during hospitalization or before the onset of colon preparation (rise of creatinine more than 0.3 or GFR reductions by 50% in the last 3-4 days), 3. Oliguria and symptoms of dehydration (urine output < 0.5 cc/kg/hour in the last six hours), 4. Any contraindications for colonoscopy, 5. Any severe mental retardation, 6. Pregnancy and breast feeding

Intervention groups

The intervention group received fluid containing Senozoid (90 mg) and 1000 ml of PEG (totally 1100 ml) every 12 hours, 24 hours before colonoscopy. The control group received 100 ml of water and 1000 ml of PEG

(totally 1100 ml). The containing boxes was were the same and without label.

Main outcome variables

Blood Urea Nitrogen(BUN), Ceratinin(Cr), Sodium(Na), Potasium(K), Col on clearance rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180412039283N2**
Registration date: **2021-03-10, 1399/12/20**
Registration timing: **registered_while_recruiting**

Last update: **2021-03-10, 1399/12/20**

Update count: **0**

Registration date

2021-03-10, 1399/12/20

Registrant information

Name

meghdad sedaghat

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8863 7168

Email address

sedaghat@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-05, 1399/12/15

Expected recruitment end date

2021-09-06, 1400/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of low dose PEG (polyethylene glycol) and low dose PEG with Sena grafín regarding bowel preparation quality in patients with chronic kidney disease

Public title

Investigation of the Effect of Senagraph on colon preparation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with Chronic Kidney Disease (GFR<60) who are candidates for colonoscopy

Exclusion criteria:

Patients needing dialysis or Patients with a GFR of less than 15 (Base on MDRD)

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **122**

Randomization (investigator's opinion)

Randomized

Randomization description

We used block randomization method. Each block size was 2 by 2, and in total 16 blocks were considered. The sequence for packages within each block were: ABBA_BABA_BBAA_ABAB_AABB_BAAB. Then each were marked from 1 to 6 as above. After that the packages within blocks were sequentially numbered from 1 to 64. The random number generator program was used.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Patients and the ward staff who delivered the medicine to the patients and the doctor who performed the colonoscopy were unaware of the type of medicine. The analyst was also unaware of the type of preparation given during the analysis. One group received fluid containing Senozoid (90 mg) and 1000 ml of PEG (totally 1100 ml) while the other group received 100 ml of water and 1000 ml of PEG (totally 1100 ml). The containing

boxes were the same and without label.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Koodakyari street. velenjak

City

Tehran

Province

Tehran

Postal code

1234569871

Approval date

2019-11-19, 1398/08/28

Ethics committee reference number

IR.SBMU.MSP.REC.1398.803

Health conditions studied

1

Description of health condition studied

Chronic Kidney Disease

ICD-10 code

N18

ICD-10 code description

Chronic kidney disease (CKD)

Primary outcomes

1

Description

bowel preparation quality base on Ottawa score

Timepoint

24 hours after receiving the solution

Method of measurement

perform colonoscopy and determine the Ottawa score

Secondary outcomes

1

Description

Blood Urea Nitrogen (BUN)

Timepoint

Before the intervention, 24 hours and 48 hours after the intervention

Method of measurement

Blood biochemistry test

2

Description

Ceratinin(Cr)

Timepoint

Before the intervention, 24 hours and 48 hours after the intervention

Method of measurement

Blood biochemistry test

3

Description

Sodium(Na)

Timepoint

Before the intervention, 24 hours and 48 hours after the intervention

Method of measurement

Blood biochemistry test

4

Description

Potassium(K)

Timepoint

Before the intervention, 24 hours and 48 hours after the intervention

Method of measurement

Blood biochemistry test

Intervention groups

1

Description

"Intervention group": Patients in this group received a solution containing one and a half glasses of Senagraf syrup every 12 hours, each glass of which contained 60 cc and 90 mg of SENOZOID, and with 1000 cc of polyethylene glycol solution. In total it was about 1100 cc of oral solution, received 24 hours ago of colonoscopy

Category

Treatment - Drugs

2

Description

"Control group": Patients in this group received a solution containing 1000 cc of polyethylene glycol solution and 100 cc of water (1100 cc in total) every 12 hours, 24 hours before colonoscopy.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Hossein hospital

Full name of responsible person

Meghdad Sedaghat

Street address

Nezamabad, Madani street, Emam Hossein hospital

City

Tehran

Province

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Postal code

1234567890

Phone

+98 21 7343 0000

Email

sedaghat@sbmu.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Ali Ziai

Street address

Koodakyari street, velenjak

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Tehran

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1234567890

Phone

+98 21 6466 3443

Email

mpd@sbmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Meghdad Sedaghat

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Meghdad Sedaghat

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Meghdad Sedaghat

Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

All data is shared after unidentifiable people

When the data will become available and for how long

6 months after printing the results

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

Use data to compare with other similar interventions

From where data/document is obtainable

Farzaneh tolouei farzanehtolouei@yahoo.com

What processes are involved for a request to access data/document

Email request

Comments