Queen Elizabeth Hospital
Department of Medicine
PICO-PEG trial
Patient Information Sheet

Title: Efficacy, tolerance and safety of split dose bowel preparation for colonoscopy: 4L polyethylene glycol (PEG) versus 1L polyethylene glycol plus Sodium picosulfate-magnesium citrate (SPMC) (PICO-PEG Trial)

Principal Investigator: Dr. Tso Yau Kan

Introduction

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Feel free to ask if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you.

Background

Upon consent for colonoscopy, doctor will provide you guidance on diet restriction and prescribe medication in order to cleanse your bowel. Adequate bowel preparation is one of the prerequisite for a safe and effective colonoscopy. High volume polyethylene glycol (PEG) is the gold standard for bowel preparation. However, it is poorly tolerated and may deter patients from receiving further colonoscopy.

Combination of PEG with different bowel preparation agent is useful to reduce the total volume, improve compliance and tolerance of patients undergoing colonoscopy. Sodium picosulfate magnesium citrate (SPMC) is another laxative agent for bowel preparation. It is a mixture of sodium picosulfate 0.01g, magnesium oxide 3.5g and citric acid 12.0g. This preparation has the advantage of smaller volume and better palatability, yet equally effective in colon cleansing, leading to better tolerance, safer and higher rate of successful

colonoscopy. SPMC is one of the choice of bowel preparation in QEH, however it does have side effects such as dehydration and electrolyte disturbance if not taken precaution.

We hypothesize that bowel preparation using combination of SPMC+PEG is better tolerated than PEG, with similar bowel cleansing ability and safety.

What is the purpose of this study

This study aims to evaluate the efficacy, tolerance and safety of two different bowel preparation for colonoscopy: 4L polyethylene glycol (PEG) versus 1L PEG + Sodium picosulfate-magnesium citrate (SPMC).

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this patient information sheet to keep and be asked to sign a patient informed consent form. However, you are free to withdraw any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the present and future standard of care you receive. If you withdraw from the study, the data collected up to your withdrawal will not be used unless with your consent. You may also express your consent to research team through Informed Consent Form to allow research team to continuously use data collected before your withdrawal for research purpose. You can take time to decide whether or not you wish to take part. If you decide to participate, you need to sign a patient informed consent form. By signing a written informed consent form, you will be given a patient information sheet and a signed copy of this patient informed consent form for record.

Why have I been chosen?

You have been invited to participate in this study because you are having colonoscopy for the first time.

What will happen to me if I take part?

If you participate in this study, you will be randomly divided (ratio: 1 to 1) into two groups, the study group (1L PEG and 2 sachets SPMC) and the control group (4L PEG). Once

allocated, participants are not allowed to switch study group.

Medication for study group (1L PEG and 2 sachets SPMC)

Patients allocated to the study group shall mix each sachet of SPMC in 150ml warm water. The patient shall take the 1st dose at 4pm the day before procedure followed by 1250ml clear fluid before the next dose. The 2nd dose shall be taken around 10pm and followed by at least 750ml clear fluid before bed. On 7am the day of procedure, they shall take 1L PEG in 1 hour (They shall dissolve 1 sachet of PEG in 1L water).

Medication for control group (4L PEG)

Patients allocated to the control group shall mix two sachets of PEG in 2L water. At 6pm the evening before examination, they shall consume 250ml solution every 15mins, and finish in 2hours. At 7am the day of examination, drink another 2L PEG in 2 hours.

We will collect information from two groups of participants, regarding your sex and age, past medical history, history of prior surgery, current medications and reason for colonoscopy. Day ward staff will collect the questionnaire from you before proceeding to colonoscopy. Unfilled answer will be analyzed and adjusted in the study.

Before colonoscopy	You will be given this information sheet and explanation regarding the clinical trial. If you decide to participate, you will sign a patient informed consent form and collect the assigned bowel preparation.
3 days before colonoscopy	Diet modification as suggested on information sheet
1 day before colonoscopy	Start taking the assigned bowel preparation.
On day of colonoscopy	Finish the rest of bowel preparation. You will be admitted to day ward and given a questionnaire to fill in before proceed to colonoscopy. (The questionnaire will collect your opinion during and after the consumption of bowel preparation. It will take less than 5 minutes to finish.)
After colonoscopy	You will be monitored for any adverse effects and complications for 2 hours in the day ward before discharge.

What are the possible benefits?

You will not receive any direct benefits from participating this study, but it will help researcher to gain better insight for the choice of bowel preparation; which will eventually result in improved patient care.

What are the potential risks and discomforts?

After taking the bowel preparation, some people may develop nausea and abdominal bloating. SPMC may cause electrolyte disturbance such as low blood sodium and high blood magnesium.

Are there alternative treatments?

You may choose not to participate in this study, and this decision will not affect your scheduled colonoscopy.

You will be prescribed our usual standard protocol for colonoscopy bowel preparation, which is 3-4L PEG.

Will I receive any expenses and payments?

Except hospital maintenance fees, you are not required to pay extra fees for joining the study, and you will not receive any reward.

Compensation and treatment for study related injury

If participation in this study has caused you any physical injury or uncomfortable emotion, the investigator will treat you or refer you for treatment. You are not giving up any of your legal rights by signing this form.

Circumstances under which your participation in the Research will be terminated

If you encountered any discomfort during your bowel preparation, you have the right to request termination of colonoscopy and participation of the study.

Will information about me be kept confidential?

Your confidentiality will be the highest priority. If the information you provide is reported or published, this will be done in a way that does not identify you as its source. To ensure the

highest form of confidentiality, we do not fill in your name on the questionnaire.

Under the laws of Hong Kong (in particular the Personal Data (Privacy) Ordinance, Cap 486), you enjoy or may enjoy rights for the protection of the confidentiality of your personal data, such as those regarding the collection, custody, retention, management, control, use (including analysis or comparison), transfer in or out of Hong Kong, non-disclosure, erasure and/or in any way dealing with or disposing of any of your personal data in or for this study. For any query, you should consult the Privacy Commissioner for Personal Data or his officer (Tel no.: 2827 2827) as to the proper monitoring or supervision of your personal data protection so that your full awareness and understanding of the significance of compliance with the law governing privacy data is assured.

By signing a written patient informed consent form, you are authorizing the Research Ethics Committee (REC) and the regulatory authority(ies) will be granted direct access to your study data for data verification.

How will my personal data be stored?

Your signed patient informed consent form will be stored separately from your personal data to further protect your confidentiality. Access to the data will be restricted to the researchers of this study. Along with this, all information will be stored in the computers which are only accessible by the researchers. Data can be withdrawn and destroyed if requested by you and all data will be destroyed three years after the completion of the study.

What if I have questions?

You can contact our investigator Dr Tso Yau Kan, Resident, Department of Medicine, Queen Elizabeth Hospital at 35067479 for questions related to the present study.
If you have questions related to your rights as a research participant, please contact Research Ethics Committee (Kowloon Central/Kowloon East) at 3506 8888.

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Patient Informed Consent Form

Title: Efficacy, tolerance and safety of split dose bowel preparation for colonoscopy: 4L polyethylene glycol (PEG) versus 1L polyethylene glycol plus Sodium picosulfate-magnesium citrate (SPMC) (PICO-PEG Trial)

I have reached the age of 18. I hereby give my consent to participate in the above clinical trial. I understand the study will collect information surrounding my medical history. Signing this patient informed consent form indicated that I have read this consent, that my questions have been answered to my satisfaction, and that I voluntarily agree to participate in this research study.

I acknowledge that the purpose of the undertaking and methods of the study have been fully explained to me. Moreover, I understand and have been explained the advantages, disadvantages and risks involved in the study. My personal information will be kept confidential. I understand that this study has been approved by the Research Ethics Committee (Kowloon Central/Kowloon East). I hereby consent to participate in the research study.

I understand that I can withdraw from the study at any time and this will not have any consequence on my present and future subsequent treatment. If I request to withdraw from this study, I agree / disagree my research data provided before my withdrawal will be continuously used by the investigator. I understand that if I later withdraw from the study, no further data would be collected, or any other research procedures carried out. I will receive a copy of this signed consent form.

I understand that my identity will be kept confidential. I agree to authorize the Research Ethics Committee (REC) and the regulatory authority(ies) a direct access to my research data for verification of clinical trial data, without violating my confidentiality, to the extent permitted by the applicable laws and regulations.

Subject's name (in block letters): _____

Subject's signature: _____ Date: _____

Impartial Witness's name (in block letters): _____

Impartial Witness's signature: _____ Date: _____

An impartial withness'signature should be included if the subject is unable to read or write

Name of person obtaining consent (in block letters): _____

Signature of person obtaining consent: _____ Date: _____

I will be given a patient information sheet and a signed copy of this patient informed consent form.