Version 2.1 dated 15 January 2023

Supplementary Material S3

SPIRIT Item32: Informed consent materials

The MACE-GPS Study

PARTICIPANT INFORMATION STATEMENT

Project title: A randomized controlled trial of early magnetically controlled capsule endoscopy for the prevention of gastrointestinal bleeding in patients at high bleeding risk undergoing percutaneous coronary intervention

Principal Investigator: Yongjian Wu, Fuwai Hospital, National Center for Cardiovascular Disease, Chinese Academy of Medical Science and Peking Union Medical College. No. 167 Beilishi Road, Beijing 100037, China. Phone: +010 88397977. Email:yongjianwu_fuwai@sina.com.

1. What is this study about?

You are invited to take part in a research study examining the effects of early magnetically controlled capsule endoscopy (MCE) in HBPCI patients for the prevention of gastrointestinal bleeding compared with conventional management. We are interested to know whether adjusting treatment strategy based on early MCE reduces the risk of gastrointestinal bleeding after PCI in HBPCI patients. We hope to use the data collected in this study to inform people about how to accurately assess and prevent gastrointestinal bleeding risk in HBPCI people.

You have been invited to participate in this study because you have expressed interest in participating in this study and determined that you are a HBPCI patient. This Participant Information Statement tells you about the research. Knowing what is involved will help you decide if you want to take part. Please read this sheet carefully and get in touch with the researchers to ask questions about anything that you

don't understand or want to know more about. Contact details can be found at the end of this information sheet. Participation in this research study is voluntary.

By giving your consent to take part in this study you are telling us that you:

√ Understand what you have read.

√ Agree to take part in the research study as outlined below.

√ Agree to the use of your personal information as described

2. Who is running the study?

The study is being carried out by the following researchers:

- Yongjian Wu, Professor, Fu Wai Hospital, Chinese Academy of Medical Sciences
- Peng Qu, Professor, The Second Hospital of Dalian Medical University
- Xianxian Zhao, Professor, Changhai Hospital, Naval Medical University
- Yida Tang, Professor, Peking University Third Hospital
- Shaobin Jia, Professor, Ningxia Medical University General Hospital
- Leisheng Ru, Professor, People's Liberation Army Peace Hospital
- Ling Tao, Professor, Xijing Hospital, Air Force Medical University
- Shenghua Zhou, Professor, Xiangya Second Hospital, Central South University
- Qing Yang, Professor, General Hospital of Tianjin Medical University
- Yue Li, Professor, The First Affiliated Hospital of Harbin Medical University
- Junxia Li, Professor, Seventh Medical Centre, General Hospital of the Chinese People's Liberation Army
- Xiang Ma, Professor, The First Affiliated Hospital of Xinjiang Medical University
- Jinghua Liu, Professor, Beijing Anzhen Hospital, Capital Medical University

- Yundai Chen, Professor, First Medical Centre, General Hospital of the Chinese People's Liberation Army
- Zhicheng Jin, Professor, Peking Union Medical College Hospital, Chinese Academy of Medical Sciences
- Jianping Li, Professor, Peking University First Hospital
- Yong He, Professor, West China Hospital, Sichuan University
- Chuanyu Gao, Professor, Huazhong Fuwai Hospital
- Guosheng Fu, Professor, Run Run Shaw Hospital, Zhejiang University
- Hui Chen, Professor, Beijing Friendship Hospital, Capital Medical University
- Haitao Yuan, Professor, Shandong First Medical University Shandong Provincial Hospital
- Jian Liu, Professor, Peking University People's Hospital

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3. What will the study involve for me?

Before you are enrolled in this study, the doctor will introduce the purpose of this study to you and ask you to sign the informed consent form. The doctor will ask you about your medical history and medication history, demographic characteristics and detailed physical examination, and do necessary auxiliary examinations to confirm whether you are suitable for participating in this study. If you pass the examination and voluntarily sign the informed consent form, the study will be carried out according to the following steps.

- You will be randomly divided into two groups, one for conventional therapy and one for early MCE. You will be assigned to the conventional treatment group or MCE group in a ratio of 1:1.

The conventional therapy group received conventional PCI, while the MCE group underwent magnetic capsule gastroscopy before PCI, and multidisciplinary consultation was conducted based on the results of MCE to adjust treatment strategy, if necessary. For example, if severe erosive gastritis, gastric and duodenal ulcers, and bleeding are detected by MCE, and the treatment strategy will be jointly agreed by gastroenterologist and cardiologist.

- Screening will be conducted strictly according to the inclusion criteria at enrollment. After enrollment, you will be visited on Day 30, Day 180 and Day 360 after PCI to record whether there is gastrointestinal bleeding and major adverse cardiovascular events. During the study, your doctor will collect relevant symptoms, signs, clinical events and adverse reactions from you. Please tell your doctor if you have any questions or discomfort during the study.
- The MCE is a painless, safe and effective method without anesthesia. Previous studies have shown that there is no significant difference in sensitivity and specificity between MCE and conventional electronic gastroscopy. MCE has the risk of capsule retention in the body, but the incidence is very low.

4. How much of my time will the study take?

Conventional treatment group don't take up your time. MCE group before MCE examination, patients are confirmed to have not eaten in 10 hours and had not consumed any colored liquid or syrup. At 1 hour before examination, study participants ingested 10 ml of simethicone (Menarini Group, Florence, Italy) as a defoaming agent to clean the stomach cavity for 40 minutes, followed by 500–1000 mL of water to fill the stomach cavity to provide a better view. Participants were also asked to wear a portable digital recorder for 4-5 hours after completing the stomach exam to obtain images of the duodenum and small intestine.

5. Who can take part in the study?

Patients are eligible to be included in this study if they are at least 18 years old and undergoing PCI for either chronic coronary syndrome or acute coronary syndrome with negative cardiac biomarkers (with a positive exercise electrocardiography or at least one severe (≥ 70%) coronary artery stenosis diagnosed by invasive coronary angiography or coronary artery CT angiography). Subjects must to fulfill at least one of the following inclusion criteria: 1) Age ≥ 75 years; 2) Previous history of peptic ulcer; 3) Previous history of gastrointestinal bleeding; 4) Hemoglobin <11 g/dL; 5) Moderate, Severe or end-stage CKD, eGFR <60 mL/min/1.73 m^2; 6) Anticipated use of long-term oral anticoagulation; 7) Liver cirrhosis with portal hypertension; 8) Active malignancy (excluding nonmelanoma skin cancer) within the past 12 month.

6. Do I have to be in the study? Can I withdraw from the study once I've started?

This study is entirely voluntary, and you are under no obligation to participate. Your decision to participate will have no bearing on your present or future interactions with the researchers or anyone else at the research Center. If you decide to participate in the study but later change your mind, you can withdraw at any time. You can do so by notifying the study coordinator (by phone or email) that you no longer wish to participate. We will not gather any further information from you if you opt to withdraw from the study. Please let us know what you want us to do with the information we've gathered on you up to that point when you withdraw. If you request it, your information will be withdrawn from our study records and will not be included in the study results until we have analyzed and published the findings.

7. Are there any risks or costs associated with being in the study?

In this study does not require you to pay any study-related fees. If you are assigned to the MCE, we will provide you with a free MCE as compensation for your participation in this study.

8. Are there any benefits to participating in this study?

During the course of the study, you will be followed up, observed and guided by professional study doctors, and you will receive close medical attention. In addition, if you are assigned to the MCE, we will provide you with a free MCE as compensation for your participation in this study. We anticipate that our results will contribute to our understanding of the characteristics of digestive tract injury in HBPCI patients and the benefits of changing treatment strategies.

MCE examination may occur capsule retention in the body. Although the chance of occurrence is extremely low, surgical removal may be required if it occurs during the MCE test. The investigator purchased medical technology clinical study liability insurance for each subject enrolled in the MCE group.

9. What will happen to information about me that is collected during the study?

During the study, we will be collecting various types of information from you. This includes demographics, laboratory tests, interventions, and follow-up questionnaires and biochemical test results. If participants are assigned to the MCE group, we will collect information about endoscopic results.

Data collected from this study will be published in journal articles and/or conference presentations in summary form without any personally identifying information. In addition, de-identified data may be shared with other researchers or research groups for the purpose of conducting extra analyses of our data, or comparing our results against similar studies. Under no circumstances will we provide identifying information (e.g. names, contact details) to other researchers.

By providing your consent, you are agreeing to us collecting personal information about you for the purposes of this research study. Your information will only be used for the purposes outlined in this Participant Information Statement, unless you consent otherwise. Your information will be stored securely and your identity/information will be kept strictly confidential, except as required by law. Study finding may be published, but you will not be individually identified in these publications.

10. Can I tell other people about the study?

Yes, you are free to tell others about this research. The investigator will decide whether or not other participants fit the inclusion criteria. At the same time, it's important to discuss research with them after you've finished all of your classes, in case your experience has an impact on them.

11. What if I would like further information about the study?

When you have read this information, please get in touch with the researchers if you have any further questions. You can contact your sub-site investigator or the principal investigator of the project at psychology. Phone: (+010) 88397977 or Email: yongjianwu_fuwai@sina.com.

12. Will I be told the results of the study?

You have the right to receive feedback on the overall results of this study. You can tell us you want feedback by checking the box below. This feedback will be provided in the form of a one-page summary of the study results. You will receive this feedback after the study is completed. In addition to the overall results of the study, if you have an MCE test, we will also provide you with details of the endoscopic results. This will be provided shortly after you complete your participation in the study.

13. What if I have a complaint or any concerns about the study?

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The study conforms with the Declaration of Helsinki and has been approved by the Human Research Ethics Committees of participating hospitals. Participating hospitals agree to conduct this study in accordance with the National Statement of Ethical Conduct for Human Research. This statement is intended to protect those who consent to participate in the study.

If you have any concerns about how this study is being run, or if you want to make a complaint to someone outside of the study, please contact Fuwai Hospital using the information provided below. Please provide the title of the study as well as the protocol number.

Ethics Office of Fuwai Hospital

Email: fuwailunli@fuwai.com

Telephone: +010 8839 6281

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The MACE-GPS Study

Informed Consent Signature Page

Thank you for taking the time to read this consent form. If you have read the participant information sheet and would like to take part, you may complete the consent process below. This document is made in duplicate, one signed copy for each of you and the hospital.

In giving my consent I state that:

- I understand the purpose of the study, what I will be asked to do, and any risks/benefits involved.
- I have read the Participant Information Statement and have been able to discuss my involvement in the study with the researchers if I wished to do so.
- The researchers have answered any questions that I had about the study and I am happy with the answers.
- I understand that being in this study is completely voluntary and I do not have to take part. My decision whether to be in the study will not affect my relationship with the researchers or anyone else at the hospital now or in the future.
- I understand that I can withdraw from the study at any time.
- I understand that personal information about me that is collected over the course of this project will be stored securely and will only be used for purposes that I have agreed to. I understand that information about me will only be told to others with my permission, except as required by law.
- I will receive an original copy of this informed consent form, signed by me and the investigator.

If you agree, please tick the box and sign your name and contact information.

☐ I give my consent to participate in this study

Subject's name: _____

*Subject's phone number:*_____

*Date:*_____

(If the subject is incapacitated or with limited capacity, the guardian's signature is required)

*Name of guardian:*_____

*Relationship between guardian and subject:*_____

*phone number:*_____

*Date:*_____

I confirm that the information in the informed consent form was correctly interpreted and understood by the subject and/or the subject's legal representative. The subject voluntarily consented to participate in the study.

*Signature of impartial witness [if applicable]:*_____

*Date:*_____

*Investigator Name:*_____

Date:_____

Note:

1. When the subject's informed consent ability is insufficient, the legal representative shall sign;

2. When the subject or his legal representative cannot read or write, at least one impartial witness must be present to witness the whole process of informed consent discussion and sign.

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