Supplemental materials

S1. Informed consent form

The original patient consent form is in Simplified Chinese language and has been translated into English for this publication.

Informed Consent Form

Site: XX – Patient: XX

Dear patient,

The doctor has preliminarily diagnosed you with Coronary Atherosclerotic Heart Disease (CHD) and has arranged to perform a Percutaneous Coronary Intervention (PCI). We will invite you to participate in a feasibility study of elective PCI Day Surgery (including Same-day Discharge after surgery). This research has been reviewed and approved for clinical study by the ethics committee of Beijing Anzhen Hospital Affiliated to Capital Medical University.

Before you decide whether to participate in this study, please read the following carefully. It can help you understand the study and why it is conducted, the procedure and duration of the study, the benefits, and the risks and discomfort that may be experienced during and after your participation in the study. If willing, you may also discuss with your relatives and friends, or ask the doctor to explain and help you make a decision.

1. Research background and purpose

1.1. Research background

In the past few decades, significant progress has been made to PCI, including the improvement of stent technology, the use of radial artery access, femoral artery closure devices, and more effective perioperative antithrombotic strategies. As the safety of PCI has improved, the routine practice of inpatient observation for uncomplicated elective PCI has also been questioned.

Several trials have evaluated the safety of same-day discharge (SDD) PCI in patients with otherwise uncomplicated procedures. Transradial coronary stenting in a randomized trial of patients undergoing transradial PCI showed no difference in major adverse cardiovascular events or major bleeding between SDD and 30-day overnight observation; outpatient elective PCI studies have also had similar findings in randomized studies of patients undergoing elective PCI via the transfemoral artery approach; numerous observational studies and meta-analyses have also resulted in similar findings. Additionally, studies have shown that PCI-SDD is cost-effective, saving healthcare systems millions of dollars annually in unnecessary nightly observations. Patient satisfaction with PCI-SDD was also higher than with overnight observation. In 2021, JACC published an expert consensus on SDD after PCI.

In the early 20th century, China began to gradually carry out day surgery for some diseases. In 2019 and 2020, the General Office of the National Health Commission recommended two catalogues of diseases suitable for day surgery, involving hundreds of diseases. The implementation of day surgery for chronic cholecystitis and bladder stones has effectively improved hospitals’ service efficiency, shortened average hospitalization stays, reduced medical expenses, and improved patient satisfaction. At present, PCI is not included in the recommended list of day surgery, and some hospitals in China are already trying to carry
out PCI day surgery in the Chinese medical system. At present, there is no medical evidence-based support to implement elective PCI day surgery in China. Whether or not elective PCI day surgery can be performed is related to hospital conditions, disease (patient) status, and the patient's own social factors. This study explores the feasibility, required conditions and benefits for both doctors and patients of PCI day surgery in medical institutions in China through multi-center cooperation led by Beijing Anzhen Hospital Affiliated to Capital Medical University.

*Definition of Day Surgery:

1) National Health Commission: A surgery or operation (excluding outpatient surgery) where the patient is admitted and discharged within 1 day (24 hours) according to the diagnosis and treatment plan; for special cases that need to be delayed in hospital due to illness, the hospital stay shall not exceed 48 hours. (Source: Notice on Printing and Distributing the Pilot Program for Day Surgery in Tertiary Hospitals (National Health Commission Medical Letter [2016] No. 306));

2) In 2003, the International Association for Ambulatory Surgery (IAAS) proposed to define ambulatory surgery as: operations where patient admission, surgery and discharge is completed within 1 working day, excluding outpatient operations performed in physicians’ clinics or hospitals.

1.2. Purpose of this Study

1) To explore the feasibility of PCI day surgery in the Chinese medical system; to verify that there is no significant difference in the occurrence of major adverse cardiovascular events 30 days post-surgery in the elective PCI day surgery group versus the non-day surgery group;

2) To explore the advantages and disadvantages of patient satisfaction (patient satisfaction score) between PCI day surgery and non-day surgery.

1.3. Study participants and numbers of patients involved:

This study is led by Beijing Anzhen Hospital Affiliated to Capital Medical University, and at least 2 other leading hospitals. Per statistical estimation, this trial is expected to enroll approximately 1,300 patients requiring coronary intervention therapy, of which 600 patients are expected to be enrolled at Beijing Anzhen Hospital Affiliated to Capital Medical University.

2. Who should not participate in the study:

- Patients with acute ST segment elevation myocardial infarction receiving emergency PCI;
- Very high-risk or high-risk non-ST segment elevation acute coronary syndrome patients;
- Pregnant patients or those diagnosed with malignant tumors;
- Patients who are participating in other clinical trials;
- Patients living alone or unattended;
- Patients whom the investigator deem inappropriate or those who do not agree to participate in PCI day surgery.
3. **What do I need to do if I participate in the study?**

3.1. Before you are enrolled in the study, the doctor will inquire and record your medical history, and check the hospital’s routine pre-operative/intraoperative/post-operative management processes for coronary heart disease intervention.

If you qualify to be a participant, you can voluntarily participate in the study after signing the informed consent form.

If you are unwilling to participate in the study, you will also receive routine treatment;

3.2. You need to complete the pre-discharge "Patient Satisfaction Survey", and then follow procedures to be discharged;

3.3. You need to receive 4 telephone follow-ups after discharge, namely:

1) On the 2nd and 3rd day after discharge: Regarding bleeding at the puncture point;
2) On the 7th and 30th day after discharge: Regarding the overall situation post-operation.

In order to support the smooth development of this clinical trial, Terumo Co., Ltd. will provide the listed surgical consumables for the patients enrolled in the clinical trial free of charge. The relevant surgical consumables include: 1) GlideSheath Slender 6F vascular sheath (Registration Certificate No.: Imported Medical Device 20183770228); 2) Hemostatic device for radial artery interventional puncture site (Registration Certificate No.: Imported Medical Device 20152663324).

3.4. Other matters requiring your cooperation:

On the 2nd, 3rd, 7th and 30th day after discharge, you must cooperate with the doctor to receive telephone follow-ups. You must truthfully answer the questions raised by the doctor over the telephone.

4. **Possible benefits of participating in the study**

This trial is an observational clinical study, mainly exploring the feasibility, surgical efficacy, patient satisfaction and suitable patient types in the Chinese medical system for PCI patients to be discharged within 24 hours. It provides data support for optimizing the allocation of medical resources, without any personal benefit to you, the patient.

5. **Possible adverse reactions, risks, discomfort and inconvenience of participating in the study**

The whole process of this study uses certified consumable products. The researchers are also experienced clinical physicians. This study is observational and without any risk. The risk comes from the surgery itself. Before you undergo the surgery, the doctor will confirm the surgical risks with you.

6. **Relevant expenses**
This study does not generate any costs related to the trial. You need to bear the costs of disease-related diagnosis and treatment, as well as the costs of treatment and examination required for the treatment of other diseases by yourself (or your medical insurance institution).

7. **Is personal information confidential?**

Your medical records (outpatient/inpatient medical records, laboratory tests, etc.) will be saved in their entirety in the medical department you visited. The doctor will record the laboratory test results on your medical record. Researchers, ethics committees and drug regulatory authorities will be allowed to access your medical records. Any public report on the results of this study will not disclose your personal identity. We will make every effort to protect the privacy of your personal medical data within the scope permitted by law.

8. **How can you get more information?**

You can ask any questions about this study at any time and get the corresponding answers. If there is any important new information during the study that may affect your willingness to continue to participate in the study, your doctor will inform you in time.

9. **You can voluntarily choose to participate and withdraw from the study**

Participation in this study is entirely up to you. You may refuse to participate in this study or withdraw from this study at any time during the course of the study. This will not affect the relationship between you and your doctor, nor will it affect your medical treatment or other interests.

For your best interests, your doctor or researcher may discontinue your participation in this study at any time during the study.

If you withdraw from the study for any reason, you may be asked about your use of the trial drug. You may also be required to undergo laboratory and physical examinations if your doctor deems it necessary.

10. **What should I do now?**

It is up to you (and your family) to participate in this study.

Before you make a decision to participate in the study, please ask your doctor as many relevant questions as possible.

Thank you for reading the above material. If you decide to participate in this study, please tell your doctor and he/she will arrange all matters related to the study for you. Please keep this information.
Informed Consent Signature Page

Name of clinical research project: Feasibility study of elective PCI Day Surgery (including Same-Day Discharge after surgery)

Research undertaken by: Beijing Anzhen Hospital Affiliated to Capital Medical University

Statement of Consent

I have read the above description of this study and have had the opportunity to discuss and ask questions about this study with my doctor. All my questions have been answered satisfactorily.

I am aware of the possible risks and benefits of participating in this study. I understand that participation in the study is voluntary. I confirm that I have had sufficient time to consider this, and understand that:

- I can always ask my doctor for more information.
- I can withdraw from this study at any time without discrimination or retaliation, and my medical treatment and rights will not be affected.

I also know that if I withdraw from the study midway, especially when I withdraw from the study due to reasons related to drugs, if I tell the doctor about the changes in my condition and complete the corresponding physical examination and laboratory tests, it will be very beneficial to the whole study.

If I need to take any other drug treatment due to changes in my condition, I will ask the doctor for advice in advance or tell the doctor truthfully afterwards.

I consent to the review of my research data by the Ethics Committee of the Drug Administration or the sponsor’s representative.

I will receive a signed and dated copy of the informed consent form.

Finally, I have decided to agree to participate in this study and promise to follow the doctor’s instructions as much as possible.

Patient’s signature:

mm / dd / yy

Contact no.:

I confirm that I have explained the details of this study to the patients, including their rights, possible benefits and risks, and provided them with a copy of the signed informed consent.

Doctor’s signature:

mm / dd / yy

Doctor’s work telephone: