

**Transepical With Transseptal Autologous CD 133+ Bone
Marrow Cell Implantation in Patient Following CABG
Surgery**

ClinicalTrials.gov ID: NCT02870933

Date: February 25th, 2020

Informed Consent Form

"Transepicardial with Transseptal Autologous CD 133+ Bone Marrow Cell Implantation in Patient Following CABG Surgery "

This time, stem cells are a modality of heart failure therapy that is currently being widely studied because it provides satisfactory results. The treatment use of stem cells is expected to improve cardiac function and also the quality of life of patients with severe heart failure.

Our research team from the adult cardiovascular surgery department intends to prove the benefits of CD133 + stem cell administration to improve the function of your heart. You are free to choose yes or no to participate in this research without coercion. If you have already decided to participate, you are also free to withdraw/change your mind at any time without any fines or sanctions.

If you are willing to participate in this research, you are asked to sign this agreement sheet in duplicate, one for you, and the other one for the researcher. The next procedure is the stem cells will be taken from your bone marrow by making a small incision followed by aspiration using a needle. This procedure is preceded by local anesthesia at the bone marrow collection site. Side effects that may develop in the action of taking bone marrow include swelling, infection, or bleeding. While the side effects that can be developed from general anesthesia include post-action nausea and vomiting to impaired cardiac and respiratory function. The preparations that have been taken will then be purified until they are ready for use. Then the administration of the stem cells will be carried out during the coronary artery bypass surgical procedure. Researchers will contact you within 6 months after the operation to carry out additional examinations in the form of MRI and take your blood venous of ± 3 cc. The provision of stem cells so far have been widely used and do not provide significant side effects.

We sincerely hope that you will participate in this research so that the results are expected to provide information on the effectiveness of stem cell administration as a therapy for heart failure and the results may be used as a reference in the management of heart failure so that it can benefit the community.

All data will be taken without revealing your identity. The confidentiality of your data and identity are protected by applicable laws and regulations and will not be shared on the public. You have the right to obtain all information relating to your participation in this research. You can also ask about research to the Hospital Research Ethics Committee National Cardiovascular Center Harapan Kita Hospital, Tel. 5681111, ext. 2837/2831 or email: irb.kometik_rsjpgdhk@gmail.com.

AGREEMENT TO PARTICIPATION IN RESEARCH
(INFORMED CONSENT)

Statement of Agreement:

All of these explanations have been conveyed to me and all my questions have been answered by researchers/doctors. I understand that if I need an explanation, I can ask the researcher/doctor in this research.

By signing this form, I agree to participate in this research

Patient's Signature: Date:

(Full name:)

Researcher's Signature:

(Full name:)

The phone number that can be contacted :

Address :