Informed Consent Form

Transcatheter Aortic Valve Replacement (TAVR) Double Balloon Valvuloplasty

Protocol Version 1, dated 17-JUL-2021

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Study Locations: Community Memorial Hospital
147 N. Brent Street
Ventura, CA 93003

California Cardiovascular and Thoracic Surgeons
168 N. Brent Street, #508
Ventura, CA 93003

Cardiology Associates Medical Group
168 N. Brent Street, #503
Ventura, CA 93003

Institutional Review Board: Community Memorial Health System Institutional Review Board
147 N. Brent Street
Ventura, CA 93003
805-948-5005

_____
Participant's Name

California Experimental Research Subject's Bill of Rights

The rights below are the rights of every person who is asked to be in a research study. As an experimental subject, I have the following rights:

1. To be told what the study is trying to find out,
2. To be told what will happen to me and whether any of the procedures, drugs, or devices is different from what would be used in standard practice,
3. To be told about the frequent and/or important risks, side effects, or discomforts of the things that will happen to me for research purposes,
4. To be told if I can expect any benefit from participating, and, if so, what the benefit might be,
5. To be told of the other choices I have and how they may be better or worse than being in the study,
6. To be allowed to ask any questions concerning the study both before agreeing to be involved and during the course of the study,
7. To be told of what sort of medical treatment is available if any complications arise,
8. To refuse to participate at all or to change my mind about participation after the study is started. This decision will not affect my right to receive the care I would receive if I were not in the study,
9. To receive a copy of the signed and dated consent form,
10. To be free of pressure when considering whether I wish to agree to be in the study.

If I have any other questions, I should ask the Principal Investigator. In addition, I may contact the Institutional Review Board, which is concerned with protection of volunteers in research projects. I may reach the committee office by calling 805-948-5005 from 9:00 AM to 5:00 PM, Monday to Friday, or by writing to *CMHS Institutional Review Board, Attn: Administration, 147 N. Brent Street, Ventura, CA 93003*.

_____ _____

Signature of Participant Date
(or Legally Authorized Representative if applicable)

Consent to be a Research Subject

You are eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of this research study, and the risks and possible benefits of participating. In the sections that follow, the word “we” means the study doctor and other research staff.

STUDY OVERVIEW

Dr. Jennifer Wan, Dr. Omid Fatemi, and their team are conducting research on the transcatheter aortic valve replacement (TAVR) procedure that you are scheduled to have. Because you are planning on having this procedure, you are being asked if you would like to participate in the study. During a TAVR procedure, a small balloon is inflated to expand the new aortic valve into position. The current practice is to inflate the balloon once. Sometimes, the balloon is inflated twice if the valve needs to be pushed open more. The purpose of this study is to find out if inflating the balloon twice, even when the aortic valve is already in a good position, leads to improved function of the valve.

You do not have to decide today whether you will participate in this study. Before you decide, you may talk to anyone you feel comfortable with about this study. There may be some terminology you are unfamiliar with or do not understand. Please ask the study doctor to stop as you go through this information at any point and they will take the time to explain. If you have more questions later, you can ask the study doctor or other members of the research team.

If there is anything in this form you do not understand, please ask questions. Please take your time to read this document all the way through. You do not have to take part in the study if you do not want to. If you do decide to take part, you can leave the study at any time.

WHAT IS INVOLVED IN THE STUDY?

If you decide to take part in this study, your participation will last for thirty days following your procedure. You will need to undergo the TAVR procedure as scheduled and are expected to attend your 30-day follow-up visit with your doctor. The study team will collect data before your procedure, during the procedure, and from your follow-up visit. This data includes your medical history, echocardiogram results, TAVR details, imaging, and other details from your hospitalization. (More information on your protected health information is below in the HIPAA Authorization.) There are no additional visits or tests required of you.

WHAT ARE THE STUDY PROCEDURES?

A study team member will take your medical history, along with a list of medications you are currently taking. Over the course of the study, you may be asked about symptoms you are experiencing or other questions that help evaluate your progress. Laboratory tests, electrocardiograms (EKG), and echocardiograms that are done before, during, or after the TAVR procedure will be routine and their results will be collected for the study. You will be monitored for complications as usual and any additional tests that are part of your regular, routine medical care will continue to be performed.

WHAT WILL BE DONE WITH MY DATA DURING THE STUDY?

Data collected during the study will be stored in a secure location and analyzed by the study team. We are obligated to protect your privacy and will not disclose your personal information (information about you and your health that identifies you as an individual e.g. name, date of birth, medical record number). When results of this study are published or presented, your identity will not be disclosed. Although all attempts will be made to keep your personal information confidential and protected to the fullest extent of the law, there is a limited possibility of a breach in confidentiality.

WILL I RECEIVE ANY RESULTS FROM THE TESTS DONE AS PART OF THE STUDY?

Results that could be important for your clinical care will be shared with you such as your 30 day echocardiogram. We will not share other results with you about the study or results regarding another participant's care.

WHAT ARE THE RISKS ASSOCIATED WITH PARTICIPATION IN THIS STUDY?

To date, there has not been a study to evaluate this specific technique involving double inflation of the balloon. Therefore, it is possible that this simple change could lengthen the procedure time, or increase the chance of the existing TAVR procedure risks:

- longer procedure time,
- increased perioperative stroke,
- increase in risk of damage to aorta,
- increased risk of damage to coronary arteries,
- malfunction of the valve or poor placement of the new valve,
- need for additional procedures including need for open heart surgery.

ARE THERE ANY BENEFITS TO TAKING PART IN THIS STUDY?

You may not directly benefit from participating in this study. A potential benefit could be improved blood flow across your valve, which in theory could indicate increased longevity of the valve and lessen the need for "re-do" procedures in the future. However, results from this study that are shared with other health care professionals may improve the care of other patients in the future. Allowing your information to be used in this study will not involve any additional costs to you. You will not receive any compensation.

DO YOU NEED TO GIVE YOUR CONSENT IN ORDER TO PARTICIPATE?

If you decide to participate in this study, you must sign this form. A copy will be given to you to keep as a record.

WHAT ARE YOUR RESPONSIBILITIES?

It is your responsibility to understand what the study is all about, and how it may affect you. You will need to follow your doctor's instructions, attend the procedure as scheduled, and keep your follow-up appointment. There are no additional responsibilities for the purpose of this study.

WHAT HAPPENS IF YOU DECIDE TO NOT TAKE PART IN THIS STUDY?

Participation in this study is completely voluntary. You do not have to take part in order to undergo the TAVR procedure or receive care. If you decide not to take part, or if you change your mind later, there will be no penalties or loss of any benefits to which you are otherwise entitled.

CAN YOU STOP YOUR PARTICIPATION IN THE STUDY EARLY?

You can stop being in the study at any time. You do not have to give a reason. Please contact the study doctor in writing (either mail or e-mail) if you would like to withdraw from the study.

Dr. Jennifer Wan
Attn: Clinical Research Coordinator, Room 2204
147 N. Brent Street, Ventura, CA 93003

-or-

jwan@californiacardiovascular.com

Please note, that should you withdraw consent, any data collected up until that point will be kept and analyzed.

FINANCIAL INFORMATION

While you are in this study, the cost of your regular medical care – procedures, medications, etc. – will be billed to you or your insurance as usual.

WILL THERE BE ANY ADDITIONAL COSTS?

There will be no additional costs to you by taking part in this study. Any imaging or laboratory testing that is conducted while you are enrolled in this study will be standard of care.

WILL YOU BE PAID FOR TAKING PART IN THIS STUDY?

You will not be paid to participate in this study.

FUNDING

There is no external or internal funding for this research. This project is being independently conducted by the investigators.

WHAT IF YOU HAVE QUESTIONS ABOUT THE STUDY?

If you have questions about this study or how your samples/data are going to be used, call the study doctor, Dr. Wan at (805)-643-2375. You may also talk to your own doctor if you have questions or concerns.

The Institutional Review Board (IRB) at Community Memorial Health System has reviewed and approved this study. The IRB looks at research studies like these and makes sure research subjects' rights and welfare are protected. If you have questions about your rights or if you have a complaint, you can call the CMHS IRB Office at 805-948-5005.

CONSENT TO TAKE PART IN THIS RESEARCH STUDY
By signing this form, you are indicating that you have had your questions answered, you agree to take part in this research study.

_____
Printed Name of Participant
(or Legally Authorized Representative)

_____ _____
Signature of Participant Date/Time
(or Legally Authorized Representative)

Person Obtaining Consent

The research study and consent form have been explained to you by:

_____
Printed Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent Date/Time

***Legally Authorized Representative* (if applicable)**

_____
Relation to Patient

***Witness* (if applicable)**

_____
Printed Name of Witness

_____ _____
Signature of Witness Date/Time

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HIPAA Authorization

Federal regulations give you certain rights related to your health information. These include the right to know who will receive the information and how it will be used. The study doctor must obtain your authorization (permission) to use or release any health information that might identify you.

WHAT INFORMATION MAY BE USED AND SHARED?
As part of this research, health information about you will be collected. This will include information from medical records, procedures, interviews and tests. Information related to your medical care at Community Memorial Hospital (CMH), California Cardiovascular and Thoracic Surgeons, and Cardiology Associates Medical Group will go in your medical record. This could include physical exams, EKGs, echocardiograms, and procedure details. Medical records are available to CMH staff. Staff will view your records only when required as part of their job. Staff are required to keep your information private. Information that could identify you will not be shared with anyone - unless you provide your written consent, or it is required or allowed by law.

WHO WILL RECEIVE INFORMATION ABOUT YOU?
By law, CMH is required to protect your health information and we will do our best to keep your personal information private and confidential. However, we cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law.

The results of this study may be shown at meetings and published in journals to inform other doctors and health professionals. All personal identification information will remain private in any publication or presentation.

Several people and organizations may review or receive your identifiable information. They will need this information to complete the research, to evaluate the results of the study, and to check that the study is being done properly. These groups include:

- Community Memorial Health System Institutional Review Board (CMHS IRB)
- the U.S. Food and Drug Administration (FDA)
- Department of Health and Human Services (DHHS) agencies
- other people from regulatory agencies and organizations that perform independent accreditation and/or oversight or research.

The research staff will only allow access to your health information to the groups listed above. By signing this document, you are authorizing Community Memorial Hospital, California Cardiovascular and Thoracic Surgeons, and Cardiology Associates Medical Group to use and/or release your health information for this research. Some of the organizations listed above may not be required to protect your information under Federal privacy laws. If permitted by law, they may be allowed to share it with others without your permission.

Your permission to use and share the information and data from this study will continue until the research study ends and will not expire. Researchers continue to analyze data for many years and it is not possible to know when they will be completely done. Note: HIPAA requires that consent forms be maintained for 6 years after the study is completed. FDA has separate requirements for maintenance of data.

WHAT IF I DECIDE NOT TO ALLOW THE USE OF MY HEALTH INFORMATION?
You do not have to sign this form. If you do not sign this form, you cannot take part in this research study.

MAY I WITHDRAW OR REVOKE (CANCEL) MY PERMISSION?
Yes. You may withdraw your permission to use and disclose your health information at any time.

You can do this by sending written notice to the study doctor stating that you have changed your mind and do not want any more of your health information collected.

Dr. Jennifer Wan
Attn: Clinical Research Coordinator, Room 2204
147 N. Brent Street, Ventura, CA 93003

-or-

jwan@californiacardiovascular.com

WHAT HAPPENS IF I WANT TO WITHDRAW MY AUTHORIZATION?
Information that has already been gathered may still be used and given to others. If you withdraw your permission, no new health information will be gathered unless you have a side effect related to the study. If you withdraw your permission, you will not be able to continue being in the research study.

If you withdraw from the study but do not withdraw your Authorization, new health information may be collected until this study ends.

WHAT WILL BE DONE WITH MY DATA WHEN THIS STUDY IS OVER?

We leave open the option to potentially use and share de-identified data for future research. They may be shared with researchers/institutions outside of CMHS. This could include for profit companies. We will not ask for your consent before using or sharing them. We will remove identifiers from your data, which means that nobody who works with them for future research will know who you are. Therefore, you will not receive any results or financial benefit from future research done on your specimens or data

MAY I REVIEW OR COPY THE INFORMATION OBTAINED OR CREATED ABOUT ME?
Yes. You have the right to review and copy your health information. However, your access to this information may be delayed until the study is complete.

Your decision to withdraw your Authorization or not to participate will not involve any penalty or loss of access to treatment or other benefits to which you are entitled.

AUTHORIZATION
By signing this form, I allow the use or disclosure of my health information. I will receive a signed and dated copy of this Authorization.

_____
Printed Name of Participant
(or Legally Authorized Representative)

_____ _____
Signature of Participant Date/Time
(or Legally Authorized Representative)