

## STUDY INFORMATION

**Study Title:** TRANSFORM-HF: Torsemide comparison with furosemide for management of heart failure

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**Site Name:** <site to insert>

**Principal Investigator:** <site to insert>

**Site Contact Information:** <site to insert>

### SHORT SUMMARY

The purpose of this research study is to compare the two most common loop diuretics, also called water pills, furosemide (“lasix”) and torsemide (“demadex”). Comparing the two diuretics will help determine which is best for patients who have heart failure. Participants who enter into the study will have their first study visit while in the hospital. Before participants start their water pill, they will be randomly chosen to take either furosemide or torsemide. All other study visits after the visit in the hospital will be done by phone. These calls are scheduled at about 30 days, then every 6 months for up to about 30 months. During the phone calls, the participant will be asked how they are feeling, the quality of their life, what medications they are taking, and if they have been back in the hospital. Participation in the study will not change regularly scheduled visits to the doctor(s).

Some risks of water pills include dizziness, lightheadedness, headache, or blurry vision. Both furosemide and torsemide can cause these side effects. Neither you nor your doctor will be able to choose which diuretic you receive. Another risk of being in this study is the loss of confidentiality. However, precautions will be taken to lower the chances of this risk.

If you are interested in learning more about this study, please continue to read below.

### PURPOSE OF THIS RESEARCH STUDY

You are being asked to be in this study because you have heart failure. Please read this consent form very carefully. Take your time when deciding whether to participate. As you go through this informed consent with your doctor or study staff who is talking to you about the study, ask them to explain any part of the consent that you do not understand. We encourage you to talk with your family and friends before you decide to be in this research study. The nature of the study, risks, discomforts, and other important information about the study are described in this document.

You should tell the study doctor or a study staff member if you are taking part in another research study.

#### Why am I being asked to take part in this study?

You have been diagnosed with heart failure. You are currently taking a water pill or will be given one as part of the treatment for your heart failure. Every year, over 5 million Americans are affected by heart failure. About 1 million Americans are hospitalized for heart failure. Having heart failure can increase the amount of water and sodium (salt) the body holds onto. This extra fluid can lead to swelling and shortness of breath.

Water pills (also called diuretic pills) are prescribed to help remove the extra fluid from the body due to heart failure. Two of the water pills most commonly ordered by doctors for patients are furosemide (also called “lasix”)

and torsemide (also called “demadex”), with furosemide being the medicine more commonly ordered. Both diuretics have been used for heart failure for more than 20 years.

### **Why is this study being done?**

While furosemide is the water pill that is usually prescribed, right now there is not enough information to tell us which water pill, furosemide or torsemide, is best for patients with heart failure. Some clinical information suggests that torsemide may be more beneficial in treating heart failure but more information is needed. This study is being done to compare these two medicines and to determine which is best for patients like you who have heart failure.

### **Who is doing this study?**

Dr. Eric Velazquez of Yale University and Dr. Robert Mentz of Duke University are leading the study, and are working with the National Institutes of Health (NIH)/National Heart, Lung, and Blood Institute (NHLBI), Yale University, and the Duke Clinical Research Institute (DCRI). The hospital in which you are currently hospitalized is participating in this study as a study site. There will be approximately 50 total study sites participating in this study.

### **How many people will take part in this study?**

About 6,000 patients who are hospitalized with heart failure will be included in this study.

## **VOLUNTARY PARTICIPATION/ POTENTIAL BENEFITS**

### **Can I say no if I don't want to be in the study?**

It is your choice to participate in this study. If you choose to not participate, your treatment for heart failure will continue as in normal practice. You will still be given water pills as needed, and your healthcare provider will choose which water pill to prescribe to you.

### **Will there be any benefit to me or others for being in the study?**

The drugs in this study are already used to treat heart failure but your physician can prescribe either of these outside of this study. Therefore, this study will not directly benefit you. However, one reason you may want to join this study is to help researchers learn about which water pill is better at treating heart failure. The results of this study may benefit patients like you in the future.

## **LENGTH OF STUDY**

### **How long will I be in this study?**

You will be in this study for at least one year after you enroll, but no more than about 30 months. Your first study visit will be done while you are in the hospital. All other study visits will be done by phone. These calls will be scheduled with you starting at about 30 days after you are enrolled, then every 6 months for up to about 30 months. We will also collect information from your medical records for the duration of the study. So that we can continue to learn how to better care for patients with heart failure, there is not a limit on the length of time we will store the information we obtain from your medical records for the purpose of the research. However, the information that might personally identify you will not be included in the records stored for future use.

### **Can I quit before my part in the study is complete?**

Yes, you can. Taking part in this study is always your choice. No matter what you decide, now or in the future, it will not affect your usual medical care.

If you decide to join this study, you can change your mind at any time. If you choose to end your participation in the study, you may contact the DCRI Call Center at 888-838-5171. After you have told us that you no longer

want to be in the study, we will not contact you, anymore. But, we will ask if you will allow us to continue to contact the doctors you see or hospitals you may visit to get information about your health.

If for some reason your healthcare provider changes the type of water pill you are taking or asks you to stop taking your water pill, you can still be in the study unless you ask us to take you out of the study.

Your study participation may also be stopped at any time by the people doing the study. If this happens, you would be told why your participation is being stopped.

## STUDY PROCEDURES

### What will I be asked to do in the study?

If you choose to participate in this study, here's what will happen after you sign this informed consent form:

#### While in the hospital:

1. Some basic information about you will be recorded, such as your age, sex, race, ethnicity, medical history, your current medications and blood test results, and your ejection fraction (which is a measurement of the blood leaving your heart each time it contracts).
2. You will also answer a few questions about how you are feeling and your quality of life.
3. The people doing the study at your hospital will complete with you a **Patient Contact Information Form**. This form will ask for information about you, such as your name, address, Social Security Number, father's last name, and contact information of family members, close friends, and your primary healthcare provider. We will use this information you provide to follow-up on your health during the time you are participating in this study. This information will only be available to your study site and assigned representatives of the Duke Clinical Research Institute (DCRI).
4. If you are a female who can become pregnant, we will ask you about your birth control methods and your menstrual history. If you are sexually active and could get pregnant, you should use birth-control during the study. If you do get pregnant, let your doctor know right away.
5. You will also be asked to sign a Medical Release Form which will give the DCRI Call Center team permission to collect medical records.
6. Before leaving the hospital, the computer will tell you and your doctor which of the two water pills you will be asked to take. You or your healthcare provider will not choose which water pill you will take. This means every participant has an equal chance of getting either of the water pills (like the flip of a coin).
7. Upon leaving the hospital, you will be given a prescription for your water pill. You will be responsible for paying for the prescription or any co-pay required by your insurance company.

#### After you leave the hospital:

1. You will receive phone calls from the DCRI Call Center research staff, starting at about 30 days, and then about every six months after that.
2. You will receive at least three phone calls, but no more than about six calls (up to about 30 months).
3. During these phone calls, you will be asked some questions, including how well you are feeling, your quality of life, if you have been back in the hospital for any reason, and if you are still taking the water pill the study chose for you. If you cannot be reached, the DCRI Call Center staff will contact the individual(s) or healthcare providers that you have listed on the Patient Contact Information Form to obtain your health information in your absence.

We may also call you for other reasons, such as to explain any information, or to give you important or new information about the study.

## ALTERNATIVES

### What are my other choices if I do not take part in this study?

If you do not wish to be in this study, you will receive your usual medical care from your health provider, which could include furosemide, torsemide, or another diuretic.

## **POSSIBLE RISKS and DISCOMFORTS**

### **What risks can I expect from taking part in this study?**

Furosemide and torsemide both can cause similar side effects such as dizziness, lightheadedness, headache, blurred vision, frequent urination, and dehydration.

However, there are no extra risks from taking your water pill as part of this study compared to taking a water pill as part of your normal care. The main differences are:

- In this study, the computer will tell you which of the two water pills to take and you have a “50-50 chance” of getting either type
- In this study, you will receive 3 to 6 phone calls from the people doing the study.

There is also a possible risk that some of your information could be seen by people who are not supposed to see it. However, we will make every effort to reduce this risk.

Your study doctor will share with you the side effects of your water pill you are given as part of this study. The side effects for the two water pills used in this study are similar.

## **FUTURE RESEARCH USE OF DATA**

### **Will the information collected from this study be used in other research studies?**

It is possible that the information collected from this study will be used in future studies.

### **What types of research will be done with my information?**

Research will be done to find out how the two water pills compare with each other for helping heart failure patients live longer, stay out of the hospital, and feel better. Research will try to find out if certain people with heart failure benefit from one water pill better than with the other. Using the information collected, research may also help us to understand the way water pills affect the heart and body of patients with heart failure.

### **Will I be paid for any future use?**

There are no plans to pay any participants in this study for the future use of their information.

### **How long will my information be stored for future use?**

There is no limit on the amount of time your health information will be stored for future research purposes. However, the information that might personally identify you will not be included in the records stored for future use.

## **WHAT IF I AM INJURED**

### **What if I am injured while taking part in the study?**

If you have a reaction or injury from the water pill you are taking, you should seek help right away. Immediate necessary medical care is available at *[medical center]* in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Yale University, Duke University, *[name of Institution(s)]*, or your study doctor to provide monetary compensation or free medical care to you in the event of a study-related injury. The cost for your treatment will be paid by you or your insurance. If you have no insurance, or if your insurance will not pay, you will need to pay these costs.

For questions about the study or research-related injury, contact Dr. [PI] at [phone number here with area code] during regular business hours or at [PI's 24-hour number with area code] after hours and on weekends and holidays.

## **PAYMENT AND COSTS**

### **Will I be paid for being in the study?**

You will not be paid for your participation in the study. No other payments made to you for participating in this study.

### **Are there costs to me for being in the study?**

There are no costs to you for being in the study. However, you will be responsible for the cost of your water pill as you normally would. If you have insurance, that may help cover the cost of your water pill. Your participation in the study should not affect the coverage. However, your insurance may require a higher or lower co-pay depending on which water pill you are assigned to.

## **PERMISSION FOR USE/DISCLOSURE OF HEALTH INFORMATION FOR RESEARCH**

### **What health information about me will be collected and shared during this study?**

Information that will be collected from you include, but is not limited to, age, sex, race and ethnicity. It will also include your current medications and blood work results, past medical history, information about current hospital stay, and your ejection fraction (which is a measurement of the blood leaving your heart each time it contracts).

### **Who will be allowed to get and use my information?**

The health and study information listed above may be shared with the following groups:

- Yale University
- Duke University/Duke Clinical Research Institute (DCRI)
- Federal Government research and health regulatory authorities
- The Institutional Review Board (IRB) overseeing this study
- Third party partners with DCRI and Yale University who will assist in monitoring study progress

Officials working for and with the above institutions or agencies may review study records to make sure we are doing things the right way. A reviewer from one of these groups who looks at your study record may also need to look at your original medical record.

The DCRI will be provided with your information that you provide, including your social security number, and will keep your contact information for follow-up purposes. The DCRI will share your contact information with the National Center for Health Statistics to obtain your vital status information.

The DCRI may also receive medical records from your hospital or other healthcare facilities or providers regarding hospitalizations you may have during your time in the study. The medical records will contain your personal information.

### **Can I change my mind about letting you use my health information?**

Yes. You may change your mind about your information being used in the study. If you change your mind about allowing your information to be used, you must withdraw your permission in writing to <insert>. Information

collected about you before you changed your mind and already shared with the groups above will continue to be used and cannot be taken back. However, no new information will be collected about you.

**When will the access to my medical record end?**

The access to your medical record for the purpose of collecting information for this study will end once the study ends.

**If I do not let you use my information, will it hurt my medical care?**

If you chose not to give your permission for health information to be used, then you cannot participate in the study. Your decision to allow your health information to be used for the study or not will not affect your medical care.

**HOW WILL MY CONFIDENTIALITY BE PROTECTED?**

There is a risk that someone could get access to study information we have stored about you and could misuse it. We think the chance of this is very small, but we can make no guarantees. Your privacy is very important to us. Here are just a few of the steps we will take to protect it:

- You will be assigned a unique code number when you enter the study
- Your name, contact information, and social security number will be available on a highly restricted basis to your clinical enrolling center and the DCRI so they can follow-up on how you are doing.
- We will store study information on secure computers available by passwords only, with many layers of security protection (i.e. firewalls). We will limit and keep track of who sees the study information to make sure it is safe.
- Other researchers who will receive study information will not know who you are. The information they get will only have the code number and not your name, contact information, or social security number.

The Department of Health and Human Services (HHS) has issued a Certificate of Confidentiality to further protect your privacy. With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

- 1) there is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);
- 2) you have consented to the disclosure, including for your medical treatment; or
- 3) the research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project or for information that is required by the Food and Drug Administration (FDA).

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. This means that you and your family must also actively protect your own privacy. Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

**CONTACT INFORMATION**

**Is there anyone I can call if I have questions or problems?**

It is important for you to know that you will continue to receive care and treatment from your own doctor. Decisions regarding your medical care will remain in the hands of your primary health care team, as usual. If you have questions or concerns about the study, you may either call your site at the contact information provided at the beginning of this consent or the DCRI Call Center at 888-838-5171.

For questions about your rights as a research participant, contact [the IRB name and contact number].

**CLINICALTRIALS.GOV**

A description of this clinical trial will be available on <https://clinicaltrials.gov/> as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this website at any time.

**STATEMENT OF CONSENT**

The purpose of this study, the procedures to be followed, the study’s risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to talk about problems, concerns, or suggestions related to the research, or to obtain information or give my suggestions about the research. I have read this consent form (or it has been read to me) and I agree to be in this study, with the understanding that I will be able to stop participating at any time. I have been told that I will be given a copy of this consent form and that a copy of this form will become part of my medical record.

I give permission for the use and disclosure of health information from my medical record to the people or groups identified in this consent form for the purposes described in this document.

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

\_\_\_\_\_  
Signature of Research Participant

\_\_\_\_\_  
Date and Time

\_\_\_\_\_  
Printed Name of Research Participant

\_\_\_\_\_  
Signature of Research Team Member Who Obtained Consent

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name of Research Team Member Who Obtained Consent