Riverside University HEALTH SYSTEM

Participant Information and Agreement to Take Part Form

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1374867-1

Principle Investigator:
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Riverside University Health System – Department of Medicine

Study Title
Does serial ultrasonography assessment for extravascular lung water and IVC measurement affect outcomes in inpatient heart failure management?

Number of study participants and use of your information:

- We plan to enroll 400 people such as yourself or your family member in our study.
- We will watch you or your family member while they are in the hospital and track them for 30 days after they leave to see if they return to the hospital.
- We plan to keep this information protected in our computers for 5 years.

Invitation to take part in a study

- You are invited to take part in this research study because you are getting treatment for heart failure (also known as CHF).
- You will not be paid any money.
- This research is to find out if ultrasound can protect your kidneys during your heart failure treatment.
- It is important that you understand the following before deciding to be part of this research
    - Reason for doing this research.
    - The possible harms and benefits.
    - What you will have to do if you decide to participate.

- Please take your time to read the information to help you decide.
- Please ask the study staff if there is anything that is not clear.
- Please ask the study staff if you would like more information.
- If you decide to take part in the study, you need to sign the 'Agreement to Take Part Form'
- If you decide not to take part in this study, your current and future medical care will not be affected in any way.

Reason for doing this study

- Heart failure symptoms are caused by extra water in your body.
- These symptoms are treated with medications to remove extra water.
- These medications work by making your kidneys to make more urine.
- One of the possible side effects of these medication is worsening kidney function.
- These medications are adjusted based on your doctor's experience and blood test results.
- The reason for this study is to find out if additional ultrasound can help your doctor to make decisions, and prevent worsening kidney function.

Deciding if you want to take part

- What happens if you decide to participate in the study?
    - You will be randomly assigned to one of two study groups.
        - Usual group: will receive the best care for your heart failure available.
        - Ultrasound group: will receive ultrasound tests in addition to the usual care.
- What happens if you say 'No"?
    - You are free to say 'No'.
    - Your decision will not affect your current and future medical care.
    - You will continue to receive the best care available.
- What if you change your mind during the study?
    - You can decide to stop participating at any time.
    - You do not have to give a reason to stop.
    - Your future care will not be affected.
    - You will continue to receive the best care available.
    - Information already collected about you cannot be deleted. This is required by the national medicine authorities. This is to make sure that the results for the study can still be used.

What do you need to know about ultrasound?

- Ultrasound uses sound waves to view inside the body.
- Ultrasound does not use radiation or x-rays.
- Ultrasound probe will be placed on your skin to get the picture.
- A layer of gel is applied to the skin to get better pictures.

What are the possible side effects of ultrasound?

- Ultrasound has excellent safety records.
- Ultrasound is considered safe when used by trained healthcare providers.
- Ultrasound wave can rarely cause warm sensation.
- Gel used in ultrasound may cause irritation or allergic reaction for some people.
- Ultrasound may discover unplanned findings. These findings may or may not be important to your health.
    - We will let your doctors know of any unplanned findings.
    - Your treating doctor will talk to you about the importance of such findings.
    - These findings may cause you stress and anxiety.
    - Extra tests may be needed to decide the importance of these findings.

What might the benefits be to you?

- You may or may not benefit from taking part in this study.
- Your participation may help other people with heart failure in the future.
- Participating in the study will not cost you extra money for additional ultrasound tests.

Who can see my information?

- Doctors involved in the study will collect information about your health and personal information.
- Your information, even if private information is removed, will not be used or given to other researchers for future research studies.
- You will not be identified by any facts that could identify the information as yours (name, birth date, contact information, gender, ethnic origin, etc.) after you are enrolled.
- Your information will be identified only when required by law.
- Study doctors will keep a code that can link you to your personal information.
- This code list will be kept at a secure and locked place.
- This information will only be available to selected members of the research team, RUHS Officials, RUHS Institutional Review board and Federal Agencies upon request.
- The code list will be kept for 5 years after the end of the study.

Who can you talk to for more information?

- Please talk to your study doctor if you have any questions, concerns or complains.
- Please use the contact information below if you feel you have been harmed as a result of taking part in this study.
    - Principle investigator: Michael T. Ulrich, MD
        - 26520 Cactus Avenue, Moreno Valley, CA 92555
        - Phone (951) 486 – 4640
- If you would like more information about your rights or would like to report a problem with this study please contact
    - RUHS IRB
        - 26520 Cactus Avenue, Moreno Valley, CA 92555
        - (951) 486 - 4462

Who is responsible for costs of the study?

- You will not be responsible for any of the costs of the ultrasound.
- You will be responsible for the standard care that is provided for our patients with heart failure.
- If we find something, we didn't think we were going to find, you may be responsible for the costs of treating that other disease.

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Agreement to Take Part Form (Informed Consent Form)

By signing this form, I agree with all the following statements:
Taking Part

- I have been given spoken and written information about this study.
- I have read and understood the information given to me.
- I had enough time to think about participating in this study.
- I have had the chance to ask questions.
- All of my questions have been answered.
- I understand that I do not have to take part in the study.
- I understand that I am free to stop my participation at any time.
- I understand that I do not have to give a reason to stop participation.
- Decision to stop my participation will not affect my future treatments.
- I understand the risks and benefits of participating in the study.

I understand the following points about my information.

- Myself or my insurance company will not be billed for any study-related ultrasounds.
- My insurance company will be responsible for additional tests my doctors order may as a result of study-related ultrasound incidental findings.
- Limited number of people can see my personal information. This is to make sure the study is done correctly.
- All personal details will be strictly confidential by all of these people.
- The people who can see my information are:
  - Staffs and doctors involved in the study
  - Institutional Review Board
- All information collected during the study is stored electronically.
- If I decided to stop taking part during the study, information already collected cannot be deleted.
- The results of this study may be made publicly available. Your personal information will be unidentified, and will not be traced to you

To be completed by you or surrogate decision maker:

I agree with all of the statements on this form and would like to take part in the study:

Signed: _____ Date/Time: _____

Name (Print): _____

To be completed by the study staff seeking the informed consent:

By signing this form, I confirm that the entire informed consent process has been conducted before any study procedures have taken place:

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Signed: _____ Date/Time: _____

Name (Print): _____