Official Title: Prospective Evaluation of 14F Thal Tube vs 28 French Chest Tube for Hemothorax and Use of Maximum Barrier Precautions
NCT03167723
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CAROLINAS HEALTHCARE SYSTEM
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Sponsor / Study Title:	**Carolinas HealthCare System / Prospective Evaluation of Chest Tube Size and Maximum Barrier Precautions**
Protocol Number:	**04-17-06**
Principal Investigator: (Study Doctor)	**Bradley W. Thomas, M.D.**
Telephone:	[redacted] **(24 hours)**
Address:	**Carolinas HealthCare System** [redacted]

This form is for use in a research study that may involve subjects who may or may not have the capacity to consent to take part in the study. Accordingly, when the subject cannot legally consent to take part, pronouns "you" and "your" should be read as referring to the subject rather than the person (legally authorized representative) who is signing and dating this form for the subject. In cases where the subject's representative gives consent, the subject should be informed about the study to the extent possible given his/her understanding. During the course of the study, if the subject regains the capacity to consent, informed consent should be completed and the subject offered the ability to leave the study if desired.

Because this is an emergency procedure, you may not be able to provide consent before the procedure has to be done. In that case, you will be given the opportunity to read and sign this consent form as soon after the procedure as possible.

INTRODUCTION

Dr. Bradley Thomas is asking you to participate in this research study because you have either a hemothorax (blood collection in the chest cavity) or you have pneumothorax (air in the chest cavity) which must be drained. The study will be evaluating the outcomes of small versus large bore (diameter or opening) thoracostomy tubes (chest tubes). In addition, the study will be evaluating the effects of specific infection control methods on the outcomes of chest tube insertion.

There is currently not enough evidence in the literature to know which size chest tube is best to drain the chest cavity in the setting of trauma. The purpose of this study, is to establish the ideal tube size and for trauma patients requiring chest tube placement. It is also to learn if certain infection control methods reduce the rate of infection as compared to historical rates.

You are being asked to take part because you have been admitted by the Trauma service and require the insertion of a chest tube as part of your care.

Your study doctor or study coordinator will go over this with you and answer any questions you may have regarding this study. Ask your study doctor or the study coordinator to explain any words or information in this consent form you do not know. Please read this paper carefully and ask questions about anything that you do not understand.

A thoracostomy is a small incision in the chest wall, that allows the insertion of a tube into the pleural space (the space between the lungs and chest wall). The pleural space is usually very small, but in your case, blood and/or air has collected in the area between the pleural membranes of the lung and the inner chest wall. Thoracostomy tubes or chest tubes are hollow plastic tubes inserted between your ribs and into the space surrounding your lungs. They are used to drain air or fluid (primarily blood) that may accumulate in the pleural space due to blunt or penetrating chest trauma. This study aims to determine whether chest tube size and maximal barrier precautions will affect the duration of tube placement, hospital length of stay, re-admission to hospital, empyema (pus in the pleural space) rates, and any need for additional surgical interventions. You will be one of approximately 645 people involved in this research project at CHS, and your participation will last for 3 months.

EMERGENCY CONSENT:

Because this is an emergency procedure, in most cases there will not be time for you to provide written consent before the chest tube is placed. However, once you are stable, you will be asked to review and sign this consent form, if you are willing to continue to participate in the study.
If you are stable enough to provide consent for receiving the chest tube before it is placed, you will be asked to review this document as well, and to sign it if you agree to be in the study.

HOW THE STUDY WORKS

If you agree to be in the study, you will be asked to sign and date a consent form.

Hemothorax Group:

A minimum of 252 people will be enrolled in this group. If you are suspected of having blood alone or a combination of blood and air in your chest cavity, you will be randomized to receive one of two study treatments by a computer software system. Being randomized means that you are put in a group by a chance process, like flipping a coin. If you are in this group, you will receive either a small (size 14 Fr) or large (size 28 Fr) chest tube. This study will be using this method because it is not clear at the present time which (study treatment) is better. Your chance of receiving either study treatment is equal. You will know which group you are in because the insertion techniques for each size differ. The small bore tube is introduced by sliding the tube over a wire that has entered the chest cavity through a needle puncture of the skin, while, the large bore catheter is inserted through an incision in the skin made with a blade.

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Pneumothorax Group
A maximum of 393 people will be enrolled in this group. The chest tube size you receive will depend on the judgement of the treating physician, and will be based on your clinical condition. The people who participate in this group will be followed to see if the extra care that will be taken to prevent infections lowers the rate of infections compared to what has been seen in the past.

Both Groups:
Standard of care guidelines will be followed during your stay. These guidelines dictate how injuries are diagnosed, treated and monitored. The guidelines will be used to determine whether you need to have a chest tube initially, and could require your having to undergo another chest tube placement if the first one is not effective enough. The decision to place a chest tube is made based on your medical history and physical exam, imaging (for example chest x-ray or CT scan) or a combination of the three. Once the doctor has put the chest tube in, it will be checked to see how much and how fast the air and fluid drains from the chest tube. If the drainage occurs too quickly or continues longer than expected, you may need to have suction added to the chest tube or you may require surgery. Once the leak has stopped and you remain stable, your study doctor will remove the tube.

Subjects in both groups will undergo chest tube placement using maximum barrier precautions. These precautions are intended to reduce the risk of infection where the chest tube enters the body. Infection precautions will include the use of hand scrubbing, gowns, masks, sterile gloves, surgical caps and drapings. All subjects in the study will have their procedure observed by a study doctor.

What will happen after the chest tube is placed?
Following insertion of the chest tube, your clinical course will be followed for three months from the day you receive a chest tube. This study will monitor how much pain you experience from the chest tube, the length of time the chest tube remains in place, your need for re-admission to the hospital, need for additional surgeries, and any development of a chest cavity infection. This study hopes to identify the optimal chest tube size for each trauma situation and outline any benefits from the addition of maximal barrier precautions when inserting chest tubes.

Your chart will be reviewed daily while you are in the hospital. Once you have been discharged, you will not have to make any additional visits specifically for the study, but you will be expected to participate in a follow up phone call about 3 months after you first had the chest tube put in. In addition, you should contact the study staff if you have to go to an emergency room or hospital within the three month period that you are in the study.

RISKS
Because you will need a chest tube for your care, you would be exposed to the risks of having a chest tube placed whether or not you participated in this study. Additional treatment and follow-up associated with the procedure are all part of standard of care.

The risks associated with this study have to do with using a smaller bore catheter as a chest tube specifically for hemothorax. It is not clear at this time whether or not the smaller size catheter could

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cause increased risk, but it is possible that the following would be more likely with the smaller catheter:

- Kinking (bending) of the tube such that it does not drain properly
- Clogging of the tube by blood clots that are too large for it to drain
- Inadequate drainage of clotted blood from the pleural space
- Need for replacement of the smaller tube by a larger tube or for an additional surgical procedure

EXCLUSION CRITERIA

Subjects who meet any of the following criteria will be excluded from the study:

- You are incarcerated
- You are pregnant
- You are under 18 years of age
- You have had a chest tube placed within the past year
- Your blood pressure and pulse are unstable, such that you require emergent chest tube placement (in less than 10 minutes from evaluation).

BENEFITS

As a result of participation in this study, your condition may improve, worsen or stay the same. The information gained from your case may benefit others with your condition.

ALTERNATIVE PROCEDURE/TREATMENT

You may choose not to participate at any time. This will not change the care you receive for your injuries. The alternative to being in this study would be to receive the usual standard of care provided to all patients needing chest tubes and the size would be up to the emergency room doctor or trauma surgeon.

ADDITIONAL COST

There will be no additional cost to you for participating in this study. All of your standard of care treatment will be billed to you or your insurance company as it normally would.

COMPENSATION

There is no monetary compensation for participating in this study.

If you become ill or are hurt while you are in the study, get the medical care that you need right away.

In the event that you are harmed as a result of your participation in this study, we will provide or arrange for treatment as necessary. This treatment, as well as other medical expenses, will be billed to you or your insurance company in the usual manner. You do not waive any legal rights by signing and dating this consent form nor does it relieve the investigators, Sponsor or involved institutions from their legal and professional responsibilities.

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WITHDRAWAL

Your participation in this study is completely voluntary. You should feel under no pressure to be in the study. If you decide not to be in the study, that will not in any way harm your relations with your doctors or with Carolinas HealthCare System. You are free to stop being in the study if you change your mind after entering it.

However, you may still require a chest tube for therapy, and should discuss that with the study doctor and any other physicians involved in your care. This would not harm your relations with your doctors or Carolinas HealthCare System.

You may be asked to stop the study even if you do not want to stop.

We will tell you about new medical findings that may affect your willingness to continue in the study.

CONFIDENTIALITY

The records of this study will be kept private. In any sort of report, we might publish, we will not include any information that will make it possible to identify a patient. Your record for this study may, however, be reviewed and/or photocopied by Carolinas HealthCare System, or by representatives of the Food and Drug Administration or other government agencies. To that extent, confidentiality is not absolute.

To ensure that your information collected for this study will be kept private, your name will not be used whenever possible. A code will be used instead of your name. All study data will be kept in a secure location.

AUTHORIZATION

If you wish to take part in this clinical study, you will be asked to sign this consent form. It allows the study sponsor and the study doctor to collect, process and pass on to the sponsor organizations any relevant personal health information collected from you during the study. These are activities routinely carried out during all clinical studies.

You have been told that personal information about you (including sensitive personal health information, such as your medical history and your racial/ethnic origin if relevant to the study) will be reviewed, collected on a computer database, stored in electronic or manual files, audited, and/or otherwise processed by:

- the study doctor (Dr. Bradley Thomas) and his study staff
- regulatory or other governmental authorities of the United States and other countries,
- other persons authorized by the study doctor,
- Carolinas HealthCare System employees,
- other persons or agencies as required by law or allowed by federal regulations.

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You have been told that your personal data are being collected and processed to:

- check your suitability to take part in the study,
- monitor your clinical course,
- compare and pool study treatment results with those of other subjects in clinical studies,

You have been told that your personal information may be processed within the U.S. or elsewhere in the world or transferred to or from the U.S. for review, processing and/or storage by an associated company or a carefully selected third-party organization.

By signing this document, you explicitly consent to the transfer of your personal information, including sensitive personal information, collected during this clinical study, for review, processing and/or storage. Your personal health information may be further shared by the groups above. If shared by them, the information will no longer be covered by the Privacy Rule. However, the groups are committed to keeping your personal health confidential.

You may refuse this authorization to transfer your personal information. If you choose not to agree to this authorization, you might be ineligible to participate in the study. If you decide not to sign this authorization, that will not harm your relations with your doctors or with Carolinas HealthCare System.

You have the right to inspect your medical record at any time. Your research record may be unavailable until the conclusion of the study. At that point, it will be available. Please speak with the study doctor if you desire to access your record.

You have been told whenever your personal information is processed; it will be kept confidential and secure, to the best of our ability. It will be used only for the purpose for which it was collected.

This Authorization does not have an expiration date. You have been told that according to the guidelines for good clinical practice, the study doctor will keep your personal information for at least 6 years. If you do not withdraw this Authorization in writing, it will remain in effect indefinitely. If you wish to revoke authorization to use your personal information, you will notify the study doctor in writing at the address and telephone number listed on the first page of this form. Some of the data obtained from your record prior to your revocation may still be used if considered necessary for the study.

FINANCIAL INTEREST OF INVESTIGATOR

None of the study doctors asking you to participate in this study have received or will receive money or other benefits for personal use from the study.

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GETTING ANSWERS TO YOUR QUESTIONS OR CONCERNS ABOUT THE STUDY

You can ask questions about this consent form or the study (before you decide to start the study, at any time during the study, or after completion of the study). Questions may include:

- Who to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a study subject;
- Eligibility to participate in the research;
- The study doctor's or study site's decision to exclude you from participation;
- Results of tests and/or procedures;
- Other questions, concerns, or complaints.

Contact the study doctor or study staff at Carolinas Healthcare, listed on the first page of this form, with any questions, concerns or complaints.

GETTING ANSWERS TO YOUR QUESTIONS ABOUT YOUR RIGHTS AS A RESEARCH SUBJECT

This study has been reviewed by an Institutional Review Board (IRB). This Committee reviewed this study to help ensure that your rights and welfare are protected and that this study is carried out in an ethical manner.

For questions about your rights as a research subject, contact:

- By mail:
  Study Subject Adviser
  [redacted]
- or call **toll free**: [redacted]
- or by **email**: [redacted]

Please reference the following number when contacting the study subject adviser: Pro00020984.

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STATEMENT OF CONSENT

I have read this form and its contents were explained to me. I agree to be in this research study for the purposes listed above. All of my questions were answered to my satisfaction. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing this form.

_____ ____/____/____ _____
Signature of Research Subject Date Time

_____
Printed Name of Research Subject

_____ ____/____/____ _____
Signature of Legally Authorized Representative (if applicable) Date Time

_____
Printed Name of Legally Authorized Representative (if applicable)

STATEMENT OF PERSON EXPLAINING CONSENT

I have carefully explained to the subject or the subject's legally authorized representative the nature and purpose of the above study. There has been an opportunity for the subject or the subject's legally authorized representative to ask questions about this research study. I have been available to answer any questions that the subject or the subject's legally authorized representative has about this study.

_____ ____/____/____ _____
Signature of Person Explaining Consent Date Time

_____
Printed Name of Person Explaining Consent

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