PLEURAL SUCTION ADITIONAL TO THORACOSTOMY TUBE FOR TRAUMATIC HEMOTHORAX

Willfredy Castano and Salin Pereira

Pablo Tobon Uribe Hospital

NCT: 2017.019

Date: Aug 18 / 2020

INFORMED CONSENT TO PARTICIPATE IN A MEDICAL INVESTIGATION STUDY

Introduction

In this document you will find all the information related to the study to which you are being invited to participate as a patient; read or listen to it carefully and carefully so that you are fully aware of accepting or refusing to participate in it; If you have doubts or questions, you have the right to ask them and have them answered regardless of when you decide to ask them.

Purpose of the research project

Trauma to the chest is associated with a high mortality rate and one of the most frequent compromises is the presence of blood around the lung (Hemothorax). It is a common emergency that can trigger short or long-term complications; such as, for example, coagulated hemothorax (presence of blood clots in the chest); which if you do not receive adequate treatment may require more complex surgeries

Treatment for Hemothorax consists of placing a drainage tube around the affected lung to drain the blood and sometimes aspirate this blood through the same hole made. Also during this tube placement, immediate blood aspiration can be performed in the hemithorax. However, sometimes this blood coagulates before it can be extracted; For this reason, we are conducting this research in which we want to evaluate if there is any difference between these two treatments

Aspiration of the pleural cavity prior to performing a thoracostomy in the patient with hemothorax due to trauma is a procedure that has been performed at our institution with some frequency. This procedure is reported in the medical literature with a work that showed that there was a decrease in the duration of the thoracostomy tube, a quantity of coagulated hemothorax as well as a decrease in infection in the thoracic cavity and additional procedures.

We have invited you to participate in the study because you have a chest trauma that caused a hemothorax, and the surgeon who treated you believes that your treatment should include a thoracostomy tube drain (chest tube drain). This research will include a total of approximately 250 patients like you, all of them from this institution

Study title: Pleural suction aditional to thoracostomy tube for traumatic hemothorax

Procedure

Since you have blood in your chest (hemothorax), you are invited to participate in this study. If you accept, you will be asked to sign this informed consent and, later, you will be assigned a type of treatment. There are only two options that are performed: 1. A drainage tube is placed in the chest, as a standard procedure, or 2. A blood aspiration is previously performed with an instrument called a cannula, which is inserted through the same place where Later the tube will be placed to the thorax, under sedation. Both procedures to be performed by a General Surgeon or a Thoracic Surgeon.

Usually the decision to perform one of these two procedures rests with the treating surgeon at his personal consideration, using either technique interchangeably, the two procedures being routine. But at this moment it is unknown if one technique is superior to the other.

This aspiration procedure will be performed under the influence of medications that decrease pain and sedation; If the bleeding is greater than established when aspirating or passing the chest tube, you will immediately have to be taken to surgery and you will leave the study. Otherwise, you will continue your manage in hospitalization, as would be done, even if you was not part of an investigation. In this hospitalization, you will be continuously monitored and a chest x-ray will be performed in the following 3 hours in order to observe the status of the lung and the position of the tube that was inserted, in addition, another x-ray will be performed within 24 hours to define possibilities of tube removal. If you are set to discharge and remove the tube, you will have an appointment a week later where you should bring in a follow-up x-ray to confirm that bleeding in the chest has resolved. If the x-rays taken during the hospitalization or the revision appointment show that the blood in your chest has not decreased or if you show any signs of complication, a CTscan will be performed to see if there is need to operate on it and It will also be evaluated by a specialist thoracic surgeon.

Participation in the investigation lasts until the review appointment 8 days after leaving the Hospital.

Risks

The fact of participating in this research does not imply any additional or different risks than those that would be had with your routine treatment. When a tube or tube is placed in the chest, there is a possibility of pain, infection, bleeding from injury to blood vessels in the chest or intrathoracic wall, as well as nerve damage. Although there is no evidence that previous aspiration with a cannula increases these risks, we presume that it could increase pain, which is why if you belong to the group of patients who, prior to inserting the tube undergo suction or aspiration, you will be given medications at the necessary doses, so that you feel as little

pain as possible and properly tolerate the procedure. In addition, there is a slight degree of sedation, generating possible amnesia from the intervention.

With this procedure you can present increased pain, infection, bleeding, nerve injury, injury to a blood vessel, need for surgery.

Benefits

The direct benefit for you would be to give you the appropriate treatment for your condition regardless of whether or not you enter the study.

Participation in the research may not offer you any additional benefits, but with your participation in the research, you are helping to define whether aspiration of the blood before placing the chest tube reduces the incidence of complications such as blood clotting, thus avoiding the need for more invasive surgical procedures, so that in the future other patients with the same complication could benefit.

Alternative procedure.

If you decide not to participate in this research, the treatment alternatives are exactly the same proposals for the research. The exams and controls will be the same, the difference is that your data would not be available for the investigation.

Confidentiality

The information of each patient in the study is private within the framework of the law, since it is mandatory to report but only under certain conditions different from those that motivate their participation in the research. In some cases and under certain conditions, the institution's ethics committee or an official body outside the hospital may request the revision

of one or more data forms. In all these situations, your identity will be kept confidential and no information about you will be released to people who are not working on this investigation

All data forms, and signed copies of these consents, will be kept in a confidential file at the coordinating data center, and only the research statistician will have access to complete information during the course of the study. The person responsible for the data is the main researcher. At the end of the study, the primary data will be kept in a confidential file and will be destroyed 5 years after the publication of the results.

Compensation

The … Hospital and the Colombian government do not have any program to provide you financial compensation if you have any complications that are not due to the investigation. Just because you agree to enter the investigation does not mean that you are giving up your legal rights

Voluntary participation

Your participation in the study is voluntary and you may decide to withdraw at any time. If you decide not to participate or if you withdraw later, you will get the same care and attention as any patient in the institution. You can ask the principal investigator or co-investigators any questions about this investigation; And you may also ask in the future if you don't understand something being done. The researchers will report any new findings to you during your study period.

Who to contact

If you have questions or complaints about the study or the personnel in charge, or think that it has not been treated appropriately, you should call the principal investigator, Dr…, email …, or directly to the ethics committee of the Institute of Medical Research of Hospital …,

phone number …. The principal investigator can answer your questions or guide you regarding the treatment in aspects related to this research.

You will not have to make any expenses during the investigation

You will not receive payment for your participation

If you have understood this document, had the opportunity to ask questions and your doubts were resolved, and you agree to participate in the investigation, please sign in the indicated place

I _____, ID number _____ city _____, I have read and understand the above information, and my questions have been answered satisfactorily. I have been informed and understand that the data obtained in the study may be published for scientific purposes. I have not received verbal, written, and / or mime pressures to participate in the study; that said decision was made in full use of my mental faculties, consciously and freely. I agree to participate in this study.

_____ _____

Patient or representative signature Date

ID number

_____ _____

Witness 1 Date

Name

Relationship

Address

_____ _____

Witness 1 Date

Name

Relationship

Address

_____

Signature of professional explaining consent