CLINICAL TRIAL PATIENT INFORMATION SHEET

"Prospective, Multicenter, Open-Label, Randomized, Phase III Clinical Trial of Prevention of Prolonged Air Leak After Lung Resection in High-risk Patients, Applying HEMOPATCH®"

The outflow of air through the pleural drains after surgery for a prolonged period of time, known as "prolonged air leak", is the most frequent technical complication of lung resection and, in addition to a risk to the patient's health, represents a considerable expense for the health system. Patients with this complication must have an intrapleural drainage for a longer time, which increases pain, anxiety and stress, as well as increasing the risk of other cardiorespiratory complications. On the other hand, it has been demonstrated that this complication is a determining cause of increased hospital stay and hospital costs. There is currently no effective treatment for this problem. None of the treatments tested has any effect on the problem of scarring of the lung tissue. The present trial will provide at-risk patients undergoing lung resection with a novel therapeutic option.

Objetive

To analyze the efficacy of the application of Hemopatch® directly on the pulmonary suture line as prevention of postoperative air leak in patients at high risk after pulmonary resection. Decrease in the postoperative air leak rate (air outflow through the drains on the 5th postoperative day).

Methods

Once included in the study, the patient will be randomly assigned to the control group (usual treatment) or to the experimental group.
The treatment of the experimental group consists in that, once the programmed pulmonary resection is completed, the experimental group will be administered up to 3 Hemopatch® patches applied at the end of the pulmonary resection on the suture lines of the pulmonary parenchyma, once the absence of air leakage has been verified.

Expected benefits

Reduction of postoperative air leakage time with the consequent reduction of discomfort and risks derived from prolonged pleural drainage. It may even happen that no benefit is obtained.

Discomfort and risks derived from the treatment

No acute toxicity or serious adverse effects have been reported with the administration of this product.

Available alternative treatments

The use of lung suture supports and other surgical adhesives. Although their routine use has shown no effect on prolonged air leak.
There is currently no effective method for the prevention or treatment of prolonged air leak in patients undergoing lung resection.

Voluntary

It is understood that your participation in the protocol is completely voluntary and that you may withdraw from it at any time, without any detriment to yourself, and without the need to give any explanation or justification. In that case you will continue to receive the same type of care and support from the medical team during your illness.

Confidential

The information obtained during your treatment will be treated confidentially and your clinical history will be identified with a number to maintain anonymity at all times. Only the physicians of the team treating you will have access to the data obtained, and your clinical history may be reviewed anonymously by the trial monitors and members of the Clinical Research Ethics Committee of the Hospital, or of the Ministry of Health, as part of any audits that may arise. The results of the study will be published in specialized journals, without ever identifying the persons who have agreed to collaborate in the trial. Your data will be included in a clinical research file, for which the center is responsible and whose purpose is to carry out research studies. You can exercise your rights of access, rectification, cancellation, opposition of data (ARCO) by contacting the center/principal investigator of this study.

Insurance

The participants in this study will be covered by an insurance policy that covers any damages that may result from the study.

At the Hospital ……. the physician(s) responsible for this study is (are) ..... will answer any questions you may have regarding the information provided or about the clinical trial. In case of emergency you can contact them or the Thoracic Surgery Department treating you by calling .....

INFORMED CONSENT DOCUMENT FOR PARTICIPATION IN THE CLINICAL TRIAL ON THE USE OF HEMOPATCH FOR THE PREVENTION OF PROLONGED AIR LEAK

LABEL
(personal identification)

I DECLARE that

DOCTOR .....me has explained
that in my situation it may be useful to apply a HEMOPATCH adhesive to the PULMONARY SUTURE.

1. The main purpose of the intervention is to decrease the time of postoperative air leakage with the consequent decrease of discomfort and risks derived from having a pleural drainage for a prolonged period of time.

2. I also understand that, at any time and without explanation, I may revoke the consent I now give.

3. I therefore declare that I am satisfied with the information received and understand the scope and risks of the treatment.

And in such conditions

I **AUTHORIZE** *THE THORACIC SURGERY SERVICE, to perform the HEMOPATCH APPLICATION in the pulmonary suture line.*

……, at .....

Doctor signature Participant signature Representative signature

REVOCATION

Mr/Ms ..... of ..... years of age.
(Name and two surnames of the patient)
with address at ..... and D.N.I. nº .....

I REVOKE the consent given on the date , and I do not wish to continue the treatment, which I hereby terminate.
In (Place and date)

Physician Patient Legal representative, family member or close relative

PATIENT'S INFORMED CONSENT TO THE CLINICAL TRIAL IN WRITING

"Prospective, Multicenter, Open-Label, Randomized, Phase III Clinical Trial of Prevention of Prolonged Air Leak After Lung Resection in High-risk Patients, Applying HEMOPATCH®"

I, ... (name and surname) declare that:

- I have read and understood the information sheet given to me.
- I have been able to ask questions about the study and they have been answered.
- I have received sufficient information about the study.

- I have talken to:_____
- (investigator)

- I understand that my participation is voluntary.

- I understand that I can withdraw from the study:
    - Whenever I want.
    - Without having to explain myself.
    - Without affecting my medical care.

- I freely agree to participate in the study.

Date Participant signature

ORAL INFORMED CONSENT OF THE PATIENT IN FRONT OF WITNESSES

"Prospective, Multicenter, Open-Label, Randomized, Phase III Clinical Trial of Prevention of Prolonged Air Leak After Lung Resection in High-risk Patients, Applying HEMOPATCH®"

I _____ (name and surnames)
declare under my responsibility that:
_____(name of study participant)

- Received and understood the information sheet about the study.
- Has been able to ask questions about the study and they have been answered.
- Has received sufficient information about the study.

- Has been informed by _____
(investigator)

- Understands that participation is voluntary.

- Understand that she/he can withdraw from the study:
    1. Whenever he/she wants.
    2. Without having to give any explanation.
    3. Without any repercussions on your medical care.

And he/she has freely expressed him/her agreement to participate in the study.

Date: Witness Signature