Study Title

Point-of-care Management of Coagulopathy in Lung Transplantation

Clinical trial number

NCT03598907

Date

01/01/2018

INFORMED CONSENT TO PARTICIPATE IN A CLINICAL STUDY

POC (Point Of Care, bedside measurement) approach to monitoring and management of coagulopathy during lung transplantation versus clinical approach and their impact on the development of PGD (primary graft dysfunction), a prospective, randomized, single-center study

Lung transplantation is a very long and demanding surgical procedure burdened with a number of possible complications. The most common complication occurring within the first 72 hours after surgery is primary graft dysfunction (PGD). It manifests as lung edema and is associated with impaired gas exchange. When it occurs, it prolongs the duration of mechanical ventilation. The procedure itself is accompanied by significant fluid loss, coagulation disorders, and often bleeding. A wide range of replacement solutions, including blood products (plasma, platelets, red blood cells), must be administered. The administration of blood products can lead to allergic reactions, increased immune response—especially in the transplanted lung—and may contribute to the development of PGD.

The aim of the study is to compare the incidence of PGD in two monitored groups after lung transplantation.

First group – the correction of coagulation disorders and replacement of circulating volume will be based on clinical assessment and therapy according to the current standard approach, using a mixture of fluids during surgery. To treat coagulation disorders and

maintain oncotic pressure, the anesthesiologist may use plasma, platelets, prothrombin complex factors, fibrinogen, etc., based on clinical experience and judgment.

Second group – for fluid replacement and maintenance of oncotic pressure, a colloid solution of 5% albumin will be used. The diagnosis and correction of coagulation disorders will be guided by POC management using ROTEM (a device-based method that assesses overall blood clotting), PFA (which measures platelet function under high flow), and Multiplate (which measures platelet function under low flow).

To date, no study has compared the efficacy of both methods in a randomized manner (randomization means randomly assigning participants into study groups). In randomization, the patient is randomly assigned to one of the two groups with equal probability (1:1).

Risks of participating in the clinical study focused on PGD and coagulation disorders

Participation in this clinical study does not present any non-standard risks to the patient. The methods used are commonly employed in the diagnosis and treatment of traumatic bleeding or liver transplantation.

What is the expected benefit of the study and why are we offering it to you?

We anticipate that targeted diagnosis and treatment of coagulation disorders using ROTEM, PFA, and Multiplate will reduce the need for blood product transfusions and thereby reduce the incidence of PGD. We believe that lowering the occurrence of PGD could result in fewer days spent on mechanical ventilation.

PATIENT PARTICIPATION AND DATA PROTECTION

Participation in the study is voluntary. The patient may withdraw at any time and will continue to receive the best possible medical care. Their personal data will be stored in accordance with Act No. 101/2000 Coll., on the protection of personal data. All data will be encoded and identifiable only by numerical code. Access to personal patient records is restricted to the investigator and authorized representatives of the clinical trial sponsor (e.g., ethics committee monitors). These individuals are bound by confidentiality. Data that could reveal the patient's identity will not leave the investigator’s site.

If you agree to participate in this study, please express your consent by signing the attached form.

INFORMED CONSENT TO PARTICIPATE IN A CLINICAL STUDY

I, the undersigned,

freely and voluntarily consent to participate in the clinical study titled: “POC (Point Of Care, bedside measurement) approach to monitoring and management of coagulopathy during lung transplantation versus clinical approach and their impact on the development of PGD (primary graft dysfunction), a prospective, randomized study.” I have been informed about the study's objectives, procedures, and what is expected of me. I understand that the study is a research activity. I acknowledge that the study is randomized and that there is a 50% chance of being placed in one of the two groups with differing diagnostic and treatment procedures. I understand that because this is a randomized study, I will not be informed of the group to which I have been assigned.

I have been informed by the physician:

MUDr. ..... (name and surname of physician)

I have been thoroughly informed about the study objectives and procedures.
I understand that I can withdraw from the study at any time. My participation is voluntary. Refusal to participate will not result in any penalty.
My personal data will be stored with full confidentiality in accordance with applicable Czech laws. Data confidentiality is guaranteed. Personal data may only be provided to third parties without identifying details, i.e., anonymized data coded by a number. For research and scientific purposes, my data may only be used anonymously or with my explicit consent. I also consent to the responsible persons accessing relevant parts of my medical records if necessary for control and data collection.

I understand that my name will never appear in reports from this study. I raise no objections to the use of results obtained from this study.

Participant's signature:
Physician's signature:

Date: .....
Date: .....

This form has been prepared in two copies. One copy is given to the study participant, and one remains with the investigator. This document is handled as confidential in accordance with applicable law.

Investigator’s initials
Patient’s initials