Mini invasive pleural probe based confocal laser endomicroscopy for malignant pleural effusion diagnosis

Study Title: Mini invasive pleural probe based confocal laser endomicroscopy for malignant pleural effusion diagnosis
Study Sponsor: CHU de Liège Sart-Tilman
Research Organization: Pneumology Department, CHU de Liège
Medical Ethics Committee: University of Liège hospital-faculty ethics committee
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NCT04731129

Patient Information and Informed Consent

Dear Sir/Madam,
You are about to undergo a pleuroscopy for your pulmonary condition management. On this occasion, we invite you to voluntarily participate in a study that focuses on the in vivo study of microscopic aspects of the thoracic cavity. The goal is to identify specific characteristics of lung diseases, including cancers. All patients with pleural effusion undergoing pleuroscopy are invited to participate in the study. However, it is important to note that you will not gain any direct benefit from your participation.

For this purpose, images will be collected using a miniature microscopy probe, which can be inserted into the biopsy channel of the endoscope (it resembles a long wire with a diameter of about one millimeter). Apart from this microscopy probe, the tools remain unchanged. First, the pulmonologist will make a small hole in your chest using a needle specifically designed for this intervention and traditionally used in this context. The microscopy probe will be inserted first through this needle. The probe is harmless and does not pose any additional risk. In the next step, the pulmonologist will enlarge the thoracic opening previously made using a surgical trocar, which is also classically used for such interventions, allowing the insertion of the operating camera. The microscopy probe will be inserted a second time through the operator channel of this camera, enabling visual control of its orientation. Therefore, the procedure is not altered in any way. The intervening pulmonologist will simply take the time to record video images using the microscopic probe at different stages of the operation, utilizing traditionally used surgical tools. It is also possible that biopsy samples will be taken as in any pleuroscopy procedure. This will allow for comparison between biopsy samples and recorded videos.

The study is titled *"Application of confocal endomicroscopy for the exploration of the pleural cavity."* All adult patients undergoing pleuroscopie for pleural effusion management are invited to participate in the study. Your pulmonologist will complete a medical form containing some of your medical record details and the results of the pleuroscopy for the proper conduct of the study. This data will be processed anonymously in accordance with the laws of December 19, 2008, and March 19, 2013, regarding the traceability of human material in biobanks and the respect of donor rights.

During the procedure, to make the tissues visible to the microscopy probe, an intravenous injection of fluorescein will be necessary. Fluorescein is a dye commonly used in everyday practice, with the side effect of temporarily causing a slight yellowish discoloration of the skin and eyes, lasting only a few hours. There is also less than 1% risk of allergic reaction to fluorescein. The rest of the procedure remains unchanged, and the use of confocal endomicroscopy only extends the procedure by about 5 minutes. You are free to withdraw from the study at any time or request the destruction of the data and/or samples concerning you. These will then not be used for comparisons with other patients or for the publication of results. You are free to decline participation in the study, and this will have no impact on your care by the medical team.

Your participation is entirely free of charge, in accordance with the law of May 7, 2004, regarding human experimentation. The sponsor assumes full liability for any direct or indirect damage caused to participants, regardless of fault, and has taken out insurance to cover this.

This study has been reviewed by the university hospital-faculty ethics committee of Liège, which has given its approval.
The endomicroscopy image sequences will be stored anonymously. Patient names will be recorded using a coding system, accessible only to the investigating physician.

If you would like more information about this study, you can contact the pneumology department at 04 366 78 81.

Informed Consent

Name:
First Name:
Date of birth:

I confirm that I have been informed about the study titled: *"*Mini invasive pleural probe based confocal laser endomicroscopy for malignant pleural effusion diagnosis*."*
I have read (or been read) all the information contained in this consent form. I acknowledge

having had enough time to ask all my questions and received satisfactory answers. I understand the nature of my participation in this research study.

I have understood the following:

- The collected images and samples will be used for a research project and stored in the database of the Pneumology Department at CHU de Liège and the hospital-university biobank of the University of Liège, respectively.
- The project has been implemented after evaluation and approval by an ethics committee.
- My participation is voluntary and free.
- I can withdraw from the study at any time, and my data and samples will be destroyed.
- The collected data will remain confidential, and my anonymity will be guaranteed when samples are processed and results published.
- There is no charge for my participation.
- I will not receive any payment for participating.
- The study sponsor has taken out insurance to cover any direct or indirect damage related to my participation.
- I can contact the investigator or a team member at any time if I need more information.
- The samples or data generated from this research could be used by a company involved in the development of health or diagnostic products.
- A fluorescein injection, a dye regularly used in practice, is necessary for the study, causing a slight yellowish discoloration of the skin and eyes for a few hours.
- These samples or generated data could also be used for other research projects, but these projects must first be approved by the hospital-faculty ethics committee of CHU de Liège.

I freely agree to participate in this study and waive any potential indirect financial benefit that may result from the research findings.

Signed in two copies at:
Signature:
Date:
Name and first name of the investigating physician:
Signature: