CathVision

Clinical Study code: PVISION – CPVI-002
Clinical study title:

AUTOMATED ASSESSMENT OF PULMONARY VEIN ISOLATION USING A NOVEL EP RECORDING SYSTEM

PATIENT INFORMATION SHEET AND INFORMED CONSENT FORM
FOR PARTICIPATION IN A CLINICAL RESEARCH CLINICAL STUDY

Sponsor:	**CathVision ApS**
Address:	**Titangade 11**
	DK-2200 Copenhagen
	Denmark

[redacted]

Summary Page

Dear Patient,

We are writing to inform you about a research study in which you are invited to participate. [redacted] This clinical study will be led by the above principal investigator (*<include name of the investigator>*) and their clinical study team.

The study has been approved by [INSERT NAME OF COMMITTEE] Research Ethics Committee and [INSERT NAME OF COMPETENT AUTHORITY] in accordance with [INSERT NAME OF LOCAL LEGISLATION IF APPLICABLE] and with European Regulation 2017/745.

This document is intended for you to receive correct and sufficient information so that you can decide whether or not to participate in this study. Please read this informed consent carefully and ask us to clarify any questions you may have. In addition, you may consult with anybody you think appropriate.

Your participation in the clinical study is voluntary. [redacted]

[redacted]

[redacted]

[redacted]

Your data will be treated confidentially, following the current legislations. [redacted]

What general things you should know about clinical studies?

Clinical studies are designed to acquire scientific knowledge that can help other people in the future. Participating in the clinical study does not necessarily bring you any direct benefit. Risks may also be associated with participation in clinical studies.

Your participation in the clinical study is voluntary. You may refuse participating in this clinical study and you may at any time and for any reason withdraw your consent to participate in any clinical study without compromising any of the rights you are entitled to, [redacted] If you are a patient with a certain disease, you do not need to participate in the clinical study to be treated.

Detailed information on this particular clinical study is provided below. It is important that you understand this information so that you can decide freely on the basis of the information received. If you provide your consent, you will receive a copy of this dated and signed consent form. You can ask the investigator listed above or the clinical study team who will assist them at any time with any question about this clinical study.

What is the purpose of this clinical study?

The purpose of this clinical study is to test a new software developed by CathVision. [redacted]

[redacted]

Why am I a candidate for this clinical study?

[redacted] You are invited to participate in the clinical study because your investigator believes that the software and CathVision Cube® can be used to safely achieve the intended clinical objectives. The CathVision Cube® system, along with its accessories, is designed to acquire, amplify, digitize, and display atrial and ventricular intracardial electro-physiological signals acquired during an electrophysiological procedure. [redacted]

[redacted]

[redacted]

Visit 1 – Screening visit (max. 30 Days before electrophysiological procedure)

You will be given the information about the clinical study, you will be given adequate time to read the information, and ask questions. If you have understood the clinical study and have agreed to participate in this clinical study, you will be asked to sign and date the Informed consent form. Signing this study consent form does not mean that you will take part in the study. You will have to meet certain requirements. If you do not meet the requirements, you will be told so.

[redacted]

Visit 2 (Electrophysiological procedure)

The following will be performed during this part of visit

- [redacted]

Visit 3 (Discharge)

The following will be performed during this part of visit

[redacted]

Are there any reasons why you should not participate in the clinical study?

You should not participate in this clinical study if any of the following apply to you:
- if you were included in another clinical study
- if you are pregnant or breast-feeding, or if you are a woman of childbearing age and do not wish to use contraceptives (such as birth control pills, IUDs, estrogen patches)

- if you are not a suitable candidate for an electrophysiological procedure in your investigator's opinion
- if you have previously had a pulmonary vein isolation procedure

How many subjects will participate in this clinical study?

A total of 90 subjects [redacted]

How long will it take me to participate?

[redacted]
The duration of the evaluation of the medical device and system during the procedure will depend only on the clinical needs associated with the treatment of your cardiac arrhythmia disorder. [redacted]
When your participation ends, you will receive the best available treatment that your doctor considers most appropriate for your disease.

What happens if you decide to participate in the clinical study?

[redacted]

After the procedure, you will be monitored in the same way as it is routinely done in patients using a commercially available tool and system.
[redacted]

What are the possible risks and inconveniences?

[redacted] Your investigator will discuss these risks with you when signing your electrophysiological procedure consent.

[redacted] For all risks, how often they will occur and how serious they are may depend upon a subject's health at the time. [redacted] Due to the non-invasive way of using it [redacted] a low incidence of complications is expected.

What happens if we learn about new risks during the clinical study?

[redacted] All such information will be provided to your principal investigator, who will provide appropriate medical care.

What are the possible benefits?

If you choose to participate in the clinical study, you will be treated or diagnosed according to standard electrophysical procedures, [redacted]

What other options do you have if you decide not to participate?

You do not need to participate in this clinical study. If you decide not to participate you will still receive a standard clinical electrophysiological procedure to treat your cardiac arrhythmia disorder.

What will happen to the data collected?

Your personal data collected as part of this clinical study will be processed in compliance with the EU Global Data Protection Regulation (GDPR) and the national regulations under the responsibility of the clinical study sponsor Cath Vision Aps, Denmark. The GDPR amends and updates the rights you have in relation to your personal data, and what companies that process your personal data are permitted and required to do. Your data will be kept as long as required by national regulations.

Under the GDPR regulations, you have the right to find out what information Cath Vision Aps, Denmark stores about you. These include the right to:

- be informed about how your data is being used;
- access personal data;

- have incorrect data updated;
- have data erased;
- stop or restrict the processing of your data;
- data portability (allowing you to get and reuse your data for different services);
- object to how your data is processed in certain circumstances.

To exercise your rights, you should contact your investigator who will then contact Cath Vision Aps, Denmark. [redacted]

Will my information be kept confidential?

Your privacy is important. All information gathered in this clinical study will be kept private. Your identity as a participant in this clinical study will be kept as confidential as possible within the law.

The information collected and analyzed by Cath Vision Aps, Denmark or its representatives should not include your name or personal data that would allow you to be identified. [redacted] Only your hospital treating doctors and nurses can identify you. [redacted]

Your personal data and the medical data resulting from your participation in this clinical study will be treated confidentially in accordance with the requirements of the EU Global Data Protection Regulation and other applicable legal requirements.

[redacted]

[redacted]

Confidentiality will be maintained at all times according to current legislation.

If you give consent, your investigator may notify your general practitioner of your involvement in this clinical study.

A description of this clinical study will be available on http://www.ClinicalTrials.gov, as required by national and international requirements. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

[redacted]

Will you be paid to participate in the clinical study?

You will not be rewarded for participating in the clinical study. [redacted] If you have any questions, please ask your investigator or the clinical study team.

Is there a cost to participate in the clinical study?

Your participation in the clinical study is not subject to any additional hospital or investigator fees.

What happens if I get pregnant during the study?

If you become pregnant during your participation in the study, you should inform your doctor immediately to receive appropriate medical care.

What happens if you are injured during your clinical study?

[redacted]

Therefore, if you believe that your health has been damaged as a result of the particular clinical study please inform your investigator or the clinical study team as soon as possible. In the event of injury to your health associated with your participation in the clinical study, you have the right for compensation under the applicable laws. If you become ill or your health is injured as a result of your participation in the clinical study, please contact the investigator immediately.
Signing of this consent form in no way represents a waiver of your legal rights, nor does it release the investigator, sponsor or involved institutions from their legal and professional duties.

What happens if you want to end your clinical study early?

Your participation in the clinical study is voluntary, so you can withdraw your consent at any time by notifying the investigator conducting the clinical study. Early termination will not entail any sanction, nor will it affect the benefits to which you are entitled and you will not lose your current or future treatment.

If you decide to stop participating in the clinical study, you should contact your investigator or the clinical study team. [redacted] Your investigator has the right to terminate your participation in the clinical study at any time. This may happen if you experience an unexpected reaction, if you do not follow the instructions, or if the clinical study is terminated.

Can the Sponsor/doctor withdraw me from the clinical study?

You should also understand that you may be withdrawn from the study if the sponsor or study investigators deem it appropriate for safety reasons, [redacted] In any case, you will receive an adequate explanation of the reason why you have been withdrawn from the study.

What are your obligations in the clinical study?

As a clinical study participant, you will be asked to comply to all clinical study requirements and visits during this clinical study. [redacted]

What if you have questions about this clinical study?

You have the right to ask any questions you may have about this clinical study and your rights. Please ask your principal investigator. If you have any further questions, concerns or complaints or if you have any health problems related to the clinical study.

What if you have questions about your rights as a clinical study participant?

This clinical study was reviewed and approved by the Ethics Committee <Ethics Committee name>. If you have any questions about your rights as a clinical study participant, you can contact

(add name)……..…Tel…….

You will be asked to read, understand and sign the Informed Consent on the following page.

AUTOMATED ASSESSMENT OF PULMONARY VEIN ISOLATION USING A NOVEL EP RECORDING SYSTEM

Patient's Informed Consent Form

I have read the information above or it has been read to me. This clinical study has been explained to me, including the potential risks and benefits associated with it. I have been given the opportunity to ask all the questions that I had, and these questions have been satisfactorily explained to me.

I understand that if I do not take part in the clinical study or decide to end my participation during the clinical study, there will be no sanctions as a consequence. I understand that this clinical study and informed consent have been checked and approved by the local EC of <Ethics Committee name>.

I voluntarily agree to participate in this clinical study and follow the instructions of the investigator. I confirm that:

1. my questions about the clinical study have been answered;
2. my GP can be informed of my participation unless I have instructed the investigator not to inform them (this request will be documented in the patient's records);
3. I can cease my participation in the clinical study at any time or withdraw my consent, and this decision will not have any impact on my future treatment;
4. the investigator can withdraw me from the clinical study at any time if I do not meet the clinical study requirements;
5. confidentiality of information shall be maintained, but my relevant personal information will be used for the purposes of the clinical study;
6. [redacted];
7. [redacted]
8. I have received a copy of this informed consent form.

_____ _____

Clinical study participant 's signature Date and time

_____

Name and surname of the participant (in capital letters)

_____ _____

Signature of the principal investigator Date and time

_____

Name and surname of the principal investigator (in capital letters)

_____ _____

Clinical study legal representative signature Date and time

_____

Name and surname of the legal representative (in capital letters)

_____ _____

Clinical study witness signature Date and time

_____

Name and surname of the witness (in capital letters)