

Patient Information Sheet for Participation in a Research Project

(This document will be signed in duplicate, with one copy retained by the investigator and the other by the patient)

Study title	SAIL-MeVO: Endovascular Treatment versus Best Medical Treatment in Distal Occlusions – Randomized Clinical Trial
Code	
Sponsor	Vall d'Hebron Institut de Recerca (VHIR) – FlowCat Lab
Coordinating Investigator	Dr. Marc Ribó, MD, PhD
Principal Investigator	
Site	
Department	Neurology/Stroke
Version	Version 1.2 – Date: 04/06/2026

Introduction

We are contacting you to provide information about a research study in which the person you represent is invited to participate. The study has been approved by a Research Ethics Committee for Medicinal Products.

The person you represent is invited to participate in a clinical research study in patients with acute ischemic stroke caused by obstruction of small- or medium-sized cerebral vessels (distal occlusions). The study has been approved by a Research Ethics Committee for Medicinal Products.

The purpose of this information sheet is to provide you with clear and sufficient information so that you can freely decide whether or not you wish the person you represent to participate. Please read it carefully and do not hesitate to ask the research team any questions. You may also discuss it with anyone you consider appropriate.

Our intention is for you to receive correct and sufficient information so that you can decide whether or not you agree for the person you represent to participate in this study. Please read this information sheet carefully, and we will clarify any questions you may have.

In addition, you may consult with anyone you consider appropriate.

Voluntary participation and right to withdraw consent:

You should know that participation of the person you represent in this study is voluntary and that they may decide not to participate or change their decision and withdraw consent at any time, without affecting their relationship with their doctor or causing any detriment to their treatment.

Ischemic stroke occurs when a blood clot blocks an artery in the brain. When the blockage affects large vessels, endovascular treatment (removing the clot using catheters) has been shown to be beneficial. However, when the obstruction is located in smaller or distal vessels, it is still unclear whether this treatment provides additional benefit over standard medical treatment.

This study aims to compare two treatment strategies:

- Best usual medical treatment.
- Best medical treatment combined with endovascular treatment adapted to distal vessels.

Objectives:

We request the participation of the person you represent in this research project, whose main objective is to determine whether endovascular treatment, added to best medical treatment, improves functional recovery at 3 months after the stroke compared with medical treatment alone.

Benefits:

Participation of the person you represent in this study may not provide a direct benefit. However, identifying possible factors related to the specification could benefit other patients who suffer from it in the future and contribute to better knowledge and treatment of this disease.

Study procedures (Specify the procedures performed as a consequence of the study)

If you agree that the person you represent participates:

- Clinical data from the medical history related to the stroke will be collected.
- Brain imaging tests (such as CT, CT angiography, or magnetic resonance imaging) will be performed; these are part of routine stroke management.
- After signing the consent form, the participant will be randomly assigned (as in a draw) to one of the two treatment groups:
 - o Standard medical treatment.
 - o Standard medical treatment plus endovascular treatment.
- Neither you nor your doctor will be able to choose the assigned group.

Clinical follow-up will take place during the hospital stay and subsequently at 30 and 90 days after the stroke, including clinical assessments and quality-of-life questionnaires. Some visits may be conducted by telephone.

The total duration of participation will be approximately 3 months.

Discomforts and possible risks arising from participation in the study:

The risks associated with the study depend on the treatment received:

- Imaging tests may involve administration of intravenous contrast, which can rarely cause allergic reactions.
- Endovascular treatment may be associated with risks such as brain bleeding, vessel injury, neurological worsening, or other complications related to the procedure. These risks are uncommon and similar to those of usual treatment in specialized centers.

The medical team will take all necessary measures to minimize these risks.

Protection of personal data:

In accordance with Regulation (EU) 2016/679 of the European Parliament and of the Council on the protection of natural persons with regard to the processing of personal data (General Data Protection Regulation, GDPR) and Organic Law 3/2018 on the Protection of Personal Data and guarantee of digital rights, the personal data collected during the study will be treated confidentially.

The data will be processed in coded form, meaning that identifying data will be replaced by a study code, so that investigators will not be able to directly identify participants. The link between this code and the participant's identity will be kept separately, securely, with access restricted to authorized center personnel.

The data controller is Hospital Universitari Vall d'Hebron / Vall d'Hebron Institut de Recerca (VHIR). The data collected will be used exclusively for scientific research purposes related to this study.

To ensure that the study is conducted correctly, the data may be reviewed by the relevant Research Ethics Committee for Medicinal Products (CEIm) and by the competent health authorities, while maintaining the confidentiality of the information.

In accordance with current regulations, you may exercise your rights of access, rectification, erasure, restriction of processing, objection, and data portability. To do so, you may contact the data controller or the institution's Data Protection Officer.

The data obtained in this study will be retained for 10 years, for the time necessary to meet the research objectives and applicable legal obligations in biomedical research.

The data will not be shared with third parties.

Contact in case of questions

If you need more information about this study, you may contact the investigator responsible, Dr. Marc Ribó, Department of Neurology, Tel. 934 893 000

Informed Consent Form

Study title:

I _____ (***patient's first and last name***) _____

I have read the information sheet that was provided to me.

I have been able to ask questions about the study.

I have spoken with: (***name of investigator***).

I understand that my participation is voluntary.

I understand that I can withdraw from the study:

1. Whenever I wish
2. Without having to give explanations
3. Without this affecting my medical care

I freely give my consent to participate in the study and confirm that I have read and agree with its contents.

I agree that the physicians responsible for this study may contact me in the future if deemed appropriate to add new data to those collected: Yes___ No___

Participant's signature

Date: ____/____/____

Investigator's signature

Date: ____/____/____

Family member/representative's signature (if applicable)

Date: ____/____/____

I wish to be informed of research findings that may be relevant to my health or that of my family members:

Yes___ No___

Telephone or e-mail contact:

I agree to the future use of my data in unrelated research: Yes___ No___

(Explanatory note: only for studies that include reuse of the data obtained for this study in future research unrelated to the research covered by this study. Unless anonymized data are used, explicit informed consent must be requested at the time consent to participate in the study is given, explaining beforehand the safeguards and guarantees that will apply.)

Participant's signature

Date: ____/____/____

Investigator's signature

Date: ____/____/____

Family member/representative's signature (if applicable)

Date: ____/____/____

**SECTION FOR REFUSAL OR WITHDRAWAL OF
INFORMED CONSENT (SIGNATURE OF THE PATIENT AND/OR FAMILY
MEMBER/REPRESENTATIVE)**

I, ...or
the family member/representative (*if applicable*) of the
patient (patient's name)
refuse/withdraw consent to participate in the study, signed above.

This withdrawal of informed consent means that from the date on which it is signed, no further medical data may be collected, without prejudice to the retention of data resulting from research that had been carried out previously.

The data resulting from research that had been carried out previously will continue to be retained.

Date of refusal/withdrawal.....

Signature: