Subject information for participation in medical research

Pelvic Venous Disorders (PeVD) – Medical Experts

Introduction

Dear Colleague,

With this information letter, we would like to ask if you are willing to participate in a scientific research. Participation is voluntary. You are receiving this letter because you are an expert in the field of Pelvic Venous Disorders (PeVD).

This letter explains the nature of the research, what it means for you and what is expected of you should you decide to participate.

Are you interested?

- Then please read this letter carefully.
- Ask any questions you may have to the researcher who provided you with this information.
- Would you like to participate? Then please complete the appendix A.

1. General information

This study is being conducted by Amsterdam UMC.

2. **What is the purpose of this study?**

Pelvic Venous Disorders (PeVD) are complex conditions involving venous reflux, obstruction, or congenital malformations within the pelvic venous system. Their diagnosis remains challenging due to overlapping symptoms, inconsistent terminology, and the lack of standardized diagnostic criteria. To address these challenges, this study seeks to establish a multidisciplinary consensus on the terminology and diagnostic approach to reflux-dominant ovarian/uterine insufficiency phenotype (V2P-R), also referred to as the ovarian/uterine reflux–insufficiency phenotype.

The study will employ a modified Delphi process, a structured method designed to achieve expert consensus through multiple rounds of anonymous input and feedback. Specialists from gynaecology, vascular surgery, interventional radiology and angiology will be invited to participate. The Delphi process will build upon insights gathered from an initial multidisciplinary focus group that will identify key challenges and unmet needs in clinical practice.

Ultimately, this Delphi study aims to provide a unified, expert-endorsed foundation for the diagnosis of V2P-R, facilitating clearer communication between specialties and improving clinical decision-making and research consistency in the field.

3. **What happens if you take part in the study?**

If you agree to take part, you will participate in an online Delphi process aimed at reaching expert consensus on the nomenclature and diagnostic criteria for reflux-dominant ovarian/uterine insufficiency phenotype (SVP: V2P-R).

The Delphi will consist of three to four rounds of online questionnaires, where you will rate statements and provide feedback based on your professional experience. After each round, anonymized group results will be shared with all participants to inform the next round.

If consensus is not reached after the questionnaire rounds, a final digital focus group may be held to discuss remaining points of disagreement. This session may be audio-recorded using a secure device from Amsterdam UMC to ensure accurate transcription. Recordings will be transcribed, anonymized, and deleted immediately after transcription.

No personal identifiers or biological materials will be collected. Any information you share will be processed confidentially and anonymously.

Each Delphi round will take about 15–20 minutes, and the optional focus group about 30–45 minutes. After the study, you will receive a summary of the findings for review and feedback (member checking). Participation is voluntary and no risks or discomfort are expected.

4. What does participation mean for you?

You will not receive any direct benefit from participating in this study.

However, your participation may contribute to greater knowledge about the diagnosis of Pelvic Venous Disorders.

5. **If you do not want to participate or wish to withdraw from the study.**

Participation in the study is entirely voluntary.

You may also decide to withdraw from the study at any time. You do not need to provide a reason for withdrawing. However, you must inform the researcher immediately if you choose to stop.

The data collected up to that point will still be used for the study.

6. **What do we do with your data?**

If you participate in the study, you also give consent for your data to be collected, used and stored.

Why do we collect, use and store your data?

We collect, use and store your data in order to answer the research questions.

The aim is to gain more insight into current diagnostic practices for Pelvic Venous Disorders (PeVD) and how these might be improved.

We intend to publish the results of the study.

The results may be published in scientific journals or presented at conferences

All Delphi rounds will be conducted under strict anonymity; the identity of individual participants will not be disclosed during any stage of the consensus process.

For any resulting scientific publication(s):

- Participants will be offered the opportunity to be listed as co-authors.
- Participants who do not wish to be listed as co-authors will have their contribution acknowledged by name in the acknowledgements section.
- Participants who prefer not to be named in any way may indicate this preference in the appropriate section of the questionnaire.

What do we do with audio recordings?

During the study, we might do an audio recording of you if a digital round is held. You are not identifiable in these recordings. We will transcribe the audio recordings. After this, the recording itself will be destroyed.

How do we protect your privacy?

To protect your privacy, we will assign a code to your data. All of your data will only be labeled with this code.

The data that directly refers to you will no longer be used. The key to the code will be kept in a secure place at the hospital. Only the researcher and members of the research team know which code belongs to you. Whenever we process or share your data, we will only use this code. In reports and publications about the study, no one will be able to trace the information back to you.

How long do we keep your data?

We will keep your data for a maximum of 10 years at Amsterdam UMC.

May we contact you again after this study for a follow-up study?

When this study is completed, we may conduct a follow-up study.
We would like to contact you at that time to ask if you would be willing to participate again. You can indicate on the consent form whether you give us permission to do so.

Would you like to know more about your privacy?
You may wish to receive an electronic copy of your personal data used in the study. That is possible. You can ask the researcher for this.
Would you like to know more about your rights regarding the processing of personal data? Then please visit**:** https://www.autoriteitpersoonsgegevens.nl/nl/over-privacy/persoonsgegevens
Do you have questions about your rights? Or do you have a complaint about your privacy? Then please contact the person responsible for processing your personal data.
If you have privacy-related complaints, we recommend discussing them first with the research team. You can also contact the Data Protection Officer of Amsterdam UMC at **privacy@amsterdamumc.nl** or submit a complaint to the Dutch Data Protection Authority (*Autoriteit Persoonsgegevens*).

7. Will you receive compensation for participating?
You will receive no compensation.

8. Do you have questions?
This study has been reviewed by the non-WMO review committee of Amsterdam UMC.
According to this committee, the study does not fall under the Medical Research Involving Human Subjects Act (WMO).
If you have any questions about this study, you can contact the physician-researcher Drs. Naila Loudini from Amsterdam UMC.

9. **Do you have a complaint?**
If you have a complaint, please discuss it with the researcher.
If you would prefer not to do so, you can contact the Patient Services Support staff.

For VUmc location:
• Phone number: 020-4440700
• Email: PAZO-VUmc@amsterdamumc.nl

For AMC location:

- Phone number: 020-5666440
- Email: PAZO-AMC@amsterdamumc.nl

For content-related questions, you can contact the researchers.

Thank you for your attention.

Contact details:

Drs. Naila Loudini

MD, PhD candidate

Gynecology and Obstetrics, Amsterdam UMC

n.loudini@amsterdamumc.nl

+31205663654

Appendix A: Participant Consent Form

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- I have read the information letter. I was also able to ask questions. My questions have been answered satisfactorily. I had enough time to decide whether to participate.
- I understand that participation is voluntary. I also understand that I can decide at any time not to participate or to withdraw from the study. I do not have to give a reason for this.
- I give permission for my data to be collected and used in the manner and for the purposes described in the information letter.
- I give permission to be contacted again after this study for a follow-up study.
- I give permission for my data to be stored for 10 years after the conclusion of this study within Amsterdam UMC.
- I agree to participate in this study.

Please tick yes or no below:

- I give permission for the collection and use of image/audio recordings. These recordings will be destroyed after they have been transcribed at the end of the study.
  O yes
  O no
- I give permission to be contacted again after this study for a follow-up research.

  O yes
  O no

Name of participant:

Signature: Date : __ / __ / __

I declare that I have fully informed this participant about the stated study.

If, during the study, new information becomes available that may affect the participant's consent, I will inform him/her in a timely manner.

Name of the physician-researcher: Naila Loudini.

Signature: Date: __ / __ / __

The participant will receive a full information letter along with a copy of the signed consent form.