# Added value of three-dimensional transvaginal ultrasound (3D TVUS) and gel infusion sonography (3D GIS) compared with magnetic resonance imaging (MRI) in the diagnosis of patients with suspicion of a uterine septum.

Submission date	Recruitment status	[X] Prospectively registered
16/10/2025	Recruiting	∐ Protocol
Registration date	Overall study status	Statistical analysis plan
17/10/2025	Ongoing	Results
Last Edited	Condition category	Individual participant data
31/10/2025	Urological and Genital Diseases	[X] Record updated in last year

## Plain English summary of protocol

Background and study aims

This study will investigate the added value of three-dimensional transvaginal ultrasound (3D TVUS) and gel contrast sonohysterography (3D GIS) for diagnosing a uterine septum compared to magnetic resonance imaging (MRI). The research will allow us to optimise the diagnostic pathway for a uterine septum.

## Who can participate?

Patients aged between 18 and 45 years with a suspected uterine septum based on a twodimensional transvaginal ultrasound.

## What does the study involve?

Participants will undergo two imaging techniques, 3D TVUS / 3D GIS and a standard pelvic MRI, to assess their diagnostic accuracy. Questionnaires regarding health and productivity will be completed after inclusion and after the final diagnosis. Questionnaires regarding patient experience will be completed 1 week after 3D TVUS / 3D GIS and 1 week after MRI.

What are the possible benefits and risks of participating?

Participation in this study offers the benefit of an additional diagnostic examination (transvaginal gel infusion sonography), which may improve the accuracy of the diagnosis. Your participation in the study could potentially help patients in the future.

The chance of experiencing any harm from participating in this study is extremely low. There is a very low risk of an allergic reaction or pelvic inflammation after a gel infusion sonography.

Where is the study run from? Ghent University Hospital, Belgium. When is the study starting and how long is it expected to run for? January 2025 to December 2028

Who is funding the study? Research Foundation Flanders (FWO), Belgium.

Who is the main contact?

Prof Tjalina Hamerlynck, septum@uzgent.be

## Contact information

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## Additional identifiers

## Clinical Trials Information System (CTIS)

Nil known

## ClinicalTrials.gov (NCT)

Nil known

## Protocol serial number

T002825N

## Study information

#### Scientific Title

SEPTUM-D project: Diagnosis in patients with a uterine septum

## Acronym

SEPTUM-D

## Study objectives

Background: Previous studies suggest that 3D transvaginal ultrasound (3D TVUS) may be a valuable alternative to MRI in the diagnosis of a uterine septum. However, large prospective studies that examine its diagnostic value are needed to determine the exact role of this technique in the diagnostic work-up of a uterine septum. Moreover, gel infusion sonography (GIS) is already frequently used in gynaecological practice for other intrauterine pathologies.

Nevertheless, its added value in the diagnosis of uterine septa has not yet been confirmed in large prospective studies.

Objective: Determining the added value of three-dimensional transvaginal ultrasound (3D TVUS) and three-dimensional gel contrast sonohysterography (3D GIS) for diagnosing patients with a suspected uterine septum by analysing sensitivity, specificity, and inter-observer reliability. by determining the sensitivity, specificity and interrater reproducibility.

## Ethics approval required

Ethics approval required

## Ethics approval(s)

approved 01/10/2025, Commissie voor medische ethiek U(Z) Gent (Corneel Heymanslaan 10, Ghent, 9000, Belgium; +32 (0)9 332 33 36; ethisch.comite@uzgent.be), ref: ONZ-2025-0219

## Study design

Prospective multicentre cohort study

## Primary study design

Interventional

## Study type(s)

Diagnostic

## Health condition(s) or problem(s) studied

Diagnosis of patients with a uterine septum

#### **Interventions**

Three-dimensional transvaginal ultrasound (3D TVUS) and three-dimensional gel infusion sonography (3D GIS).

Comparison: Magnetic resonance imaging (MRI) of the pelvis.

## Trial flow:

- 1. Suspicion of a uterine septum on 2D TVUS during routine consultation:
- Informed consent form
- Questionnaires EQ-5D-5L and iPCQ via email
- 2. Follicular phase of the menstrual cycle:
- Baseline data collection
- 3D TVUS and 3D GIS (by a gynaecologist)
- 3. 1 week after 3D TVUS/3D GIS:
- TMI questionnaires concerning patient experience of 3D TVUS and 3D GIS via telephone (by study nurse)
- 4. Within 12 weeks after inclusion:
- Pelvic MRI (by radiologist)
- 5. 1 week after MRI:
- TMI questionnaire concerning patient experience of MRI via telephone (by study nurse)

- 6. After completion of all diagnostic tests (within 14 weeks after inclusion)
- Definitive diagnosis via telephone (by a gynaecologist)
- Questionnaires EQ-5D-5L and iPCQ via email

## Intervention Type

Other

## Primary outcome(s)

The sensitivity of 3D TVUS for the diagnosis of a uterine septum compared with MRI by uterine measurements conforming to the ESHRE/ESGE, CUME, ASRM classification at 1 timepoint (when the 3D TVUS and MRI are performed)

## Key secondary outcome(s))

- 1. The specificity of 3D TVUS for the diagnosis of a uterine septum compared with MRI by uterine measurements conforming to the ESHRE/ESGE, CUME, ASRM classification at 1 timepoint (when the 3D TVUS and MRI are performed)
- 2. The sensitivity and specificity of 3D GIS for the diagnosis of a uterine septum compared with MRI by uterine measurements conforming to the ESHRE/ESGE, CUME, ASRM classification at 1 timepoint (when the 3D TVUS and MRI are performed)
- 3. The interrater reproducibility of 3D TVUS and 3D GIS for the diagnosis of a uterine septum by uterine measurements conforming to the ESHRE/ESGE, CUME, ASRM classification at 1 timepoint (after the 3D TVUS/3D GIS and MRI are performed) by a second reader.
- 4. Patient experience of 3D TVUS, 3D GIS and MRI with questionnaires using the validated survey instrument Testing Morbidities Index for 3D TVUS, 3D GIS and MRI, 1 week after each test was performed.
- 5. Cost-effectiveness of 3D TVUS and 3D GIS for the diagnosis of a uterine septum compared with MRI using the EQ-5D-5L and iPCQ questionnaires after inclusion and after final diagnosis.

## Completion date

31/12/2028

## **Eligibility**

## Key inclusion criteria

- 1. Women aged between 18 and 45 years
- 2. With suspicion of a uterine septum on routine 2D TVUS
- 3. Who are willing to give informed consent

## Participant type(s)

Patient

## Healthy volunteers allowed

No

## Age group

Adult

## Lower age limit

18 years

## Upper age limit

45 years

## Sex

**Female** 

## Key exclusion criteria

- 1. Women aged below 18 years and over 45 years
- 2. Prior definitive diagnosis of a uterine septum or other congenital uterine anomaly
- 3. Prior surgery in relation to a uterine septum
- 4. Cervical (unilateral) aplasia
- 5. Vaginal aplasia
- 6. Untreated obstructive vaginal septum
- 7. Any co-morbidity that is found to interfere with the uterine measurements required in the study
- 8. Contraindications for MRI
- 9. Not willing or not possible to undergo a transvaginal ultrasound
- 10. Pregnancy at the time of inclusion
- 11. Wish to conceive between inclusion and the last diagnostic intervention
- 12. Visual or pathological evidence of cervical, uterine or ovarian malignancy
- 13. Patients with an intrauterine device (by mistake), who are not willing to remove this device before the start of the diagnostic interventions

## Date of first enrolment

17/10/2025

## Date of final enrolment

31/12/2028

## Locations

## Countries of recruitment

Belgium

## Study participating centre Ghent University Hospital

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# Study participating centre AZ Sint-Jan Brugge

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# Study participating centre AZORG

Moorselbaan 164 Aalst Belgium 9300

## Sponsor information

## Organisation

**Ghent University Hospital** 

## **ROR**

https://ror.org/00xmkp704

## Funder(s)

## Funder type

Research organisation

## **Funder Name**

Fonds Wetenschappelijk Onderzoek

## Alternative Name(s)

Research Foundation Flanders, Flemish Research Foundation, The FWO, Het FWO, FWO

## **Funding Body Type**

Government organisation

## **Funding Body Subtype**

Trusts, charities, foundations (both public and private)

## Location

Belgium

## **Results and Publications**

## Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date

## IPD sharing plan summary

Data sharing statement to be made available at a later date

## Study outputs

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet
Participant information sheet
11/11/2025 No Yes