ISRCTN21347319 https://doi.org/10.1186/ISRCTN21347319

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
16/10/2025

Recruitment status
Recruiting

Registration date
17/10/2025

Overall study status
Ongoing

Last Edited
16/12/2025

Condition category
Urological and Genital Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[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 two-dimensional 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

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT07263984

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

Primary study design
Interventional

Study design
Prospective multicentre cohort study

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

Total final enrolment
0

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

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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, Research Foundation – Flanders, Fonds voor Wetenschappelijk Onderzoek - Vlaanderen, 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

IPD sharing plan summary
Data sharing statement to be made available at a later date