

Evaluating a single-use disposable hysteroscopic system in office hysteroscopy

Submission date 22/07/2026	Recruitment status No longer recruiting	☐ Prospectively registered ☒ Protocol
Registration date 31/07/2026	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 30/07/2026	Condition category Signs and Symptoms	☐ Individual participant data ☒ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Public, Principal investigator, Scientific

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Additional identifiers

Study information

Scientific Title
A prospective, randomized, controlled trial to evaluate the efficacy, tolerability, and feasibility of a single-use disposable hysteroscopic operating system in an outpatient office setting

Study objectives

The primary objective of this study is to evaluate the feasibility, clinical efficacy, and safety of a novel single-use disposable hysteroscopic operating system (RedPine) compared with standard reusable hysteroscopic equipment in an outpatient office setting.

Secondary objectives include evaluating operator satisfaction, procedural duration, fluid management efficiency, equipment setup time, and patient tolerability/pain perception during diagnostic and operative office hysteroscopy.

Ethics approval required

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Ethics approval(s)

Approved 10/11/2025, Ethics Committee for Clinical Trials – Tuscany Centre Local Health Authority Section (Comitato Etico per la Sperimentazione Clinica - Sezione Azienda U.S.L. Toscana Centro) (Presidio Ospedaliero di Pistoia, Via della Vergine 3, Pistoia, 51100, Italy; +39 0573 351103; giorgio.nencioni@uslcentro.toscana.it), ref: P25/059

Primary study design

Interventional

Allocation

Randomized controlled trial

Masking

Open (masking not used)

Control

Active

Assignment

Parallel

Purpose

Device feasibility, Treatment

Study type(s)

Health condition(s) or problem(s) studied

Outpatient diagnostic or operative office hysteroscopy due to suspected intra-uterine pathology

Interventions

Method of randomization:

Patients were randomly assigned (1:1 ratio) to either the experimental group (RedPine Single-Use Disposable System) or the control group (Standard Reusable System). The randomization sequence was generated prior to study initiation using a computer-generated random number software program. Allocation concealment was ensured using sequentially numbered, opaque, sealed envelopes, which were opened only immediately prior to the hysteroscopic procedure.

Study Group (single-use disposable System):

Patients undergo outpatient diagnostic or operative office hysteroscopy using the single-use

disposable hysteroscopic operating system. The system is utilized for visual evaluation of the uterine cavity and execution of targeted minor operative procedures (e.g., endometrial polyp resection, septum incision, targeted biopsies).

Reference Group (Standard Reusable System):

Patients undergo outpatient diagnostic or operative office hysteroscopy using the standard reusable hysteroscopic system currently in routine clinical use at the department, following identical clinical protocols for distension medium, access, and operative techniques.

Follow-up:

Patient pain scores and immediate post-procedural complications are assessed immediately after the procedure and prior to discharge.

Intervention Type

Device

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

RedPine single-use disposable hysteroscopic operating system, standard reusable hysteroscopic operating system

Primary outcome(s)

1. Feasibility and procedural completion rate measured using the successful completion of the hysteroscopic procedure without switching devices or aborting at intraoperative / immediately after the procedure

Key secondary outcome(s)

1. Intraoperative parameters, patient tolerability, and operator satisfaction measured using a 5-point Likert scale rated by the surgeon at post-procedure

2. Procedural duration measured using total procedure time measured in minutes at the end of the study

3. Patient pain perception measured using a Visual Analog Scale (VAS, 0–10) at immediately post-procedure

4. Fluid management and setup measured using setup time and volume of distension medium used at the end of the study

5. Adverse events measured using incidence of intraoperative and immediate post-procedural complications (e.g., vasovagal reactions, bleeding, uterine perforation) at intraoperatively and immediately post-procedure prior to discharge

Completion date

31/01/2026

Eligibility

Key inclusion criteria

1. Female patients scheduled for outpatient diagnostic or operative office hysteroscopy due to suspected intra-uterine pathology (e.g., endometrial polyps, uterine septum, abnormal uterine bleeding [AUB], or thickened endometrium)
2. Age between 18 and 80 years
3. Provided written informed consent prior to study enrollment

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 Years

Upper age limit

80 Years

Sex

Female

Total final enrolment

144

Key exclusion criteria

1. Severe pelvic organ prolapse
2. Active pelvic inflammatory disease (PID) or lower genital tract infection
3. Confirmed or suspected ongoing pregnancy
4. Inability to understand the study protocol or refusal to sign the written informed consent

Date of first enrolment

15/11/2025

Date of final enrolment

30/01/2026

Locations

Countries of recruitment

Italy

Study participating centre

Ospedale San Jacopo - USL Toscana Centro, Pistoia

Via Ciliegiole, 1

Pistoia

Italy

51100

Sponsor information

Organisation

Azienda Usl Toscana Centro

ROR

<https://ror.org/05a87zb20>

Funder(s)

Funder type

Funder Name

Azienda USL Toscana Centro

Alternative Name(s)

USL Toscana Centro Company

Funding Body Type

Government organisation

Funding Body Subtype

Research institutes and centers

Location

Italy

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			30/07/2026	No	Yes
Protocol file			30/07/2026	No	No