

Cervical preparation with a balloon device

Submission date 06/03/2026	Recruitment status Not yet recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 11/03/2026	Overall study status Ongoing	<input type="checkbox"/> Protocol
Last Edited 11/03/2026	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

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Type(s)

Scientific, Public

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Additional identifiers

Internal reference number
M360-CDD-P01

Study information

Scientific Title

Feasibility study for use of a balloon cervical dilator for cervical dilation prior to uterine evacuation

Study objectives

Ethics approval required

Ethics approval required

Ethics approval(s)

submitted 21/01/2026, Women's College Hospital REB (76 Grenville St, Toronto, M5S 1B2, Canada; +1 (0)416 351 3732 x 2723; Marie.Steele@wchospital.ca), ref: 2026-0005-E

Primary study design

Interventional

Allocation

N/A: single arm study

Masking

Open (masking not used)

Control

Uncontrolled

Assignment

Single

Purpose

Device feasibility

Study type(s)

Health condition(s) or problem(s) studied

Need for cervical dilation prior to second-trimester uterine procedures

Interventions

This is an open-label, single-arm feasibility study of a 14 mm intracervical balloon radial dilation device (M360-CDD-001-14) in participants at 13–16 weeks' gestation planning a second-trimester uterine procedure.

After informed consent, the device is placed within the cervical canal following cervical preparation, and local anesthesia; intravenous sedation is provided per site standard of care. The balloon is inflated with sterile water and then deflated and removed.

Cervical dilation is assessed after balloon removal. The planned procedure then proceeds using standard clinical practice; if dilation is inadequate or not tolerated, standard cervical preparation methods are used. Treatment consists of a single procedural episode, with a safety follow-up contact 3–7 days after device use. There is no randomization or control group.

Intervention Type

Device

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

M360-CDD-001-14

Primary outcome(s)

1. Successful cervical dilation measured using adequate dilation that is tolerated by the participant throughout the radial dilation process and does not require further cervical preparation (e.g., medications or rigid dilation) prior to uterine evacuation, assessed at end of study visit

Key secondary outcome(s)

1. Participant pain assessment measured using participant-reported pain assessment questions at during and immediately after device use at the enrollment visit

2. Investigator assessment of ease of use and participant tolerance of the device measured using investigator-completed assessment questions at following completion of the cervical dilation attempt

3. Adverse events and adverse device effects associated with balloon cervical dilation measured using clinical assessment and participant report from device use at the safety follow-up contact (3–7 days post-procedure)

Completion date

07/10/2026

Eligibility

Key inclusion criteria

1. Signed informed study consent
2. Healthy females 18 years old or more at the time of enrollment
3. Unwanted pregnancy or fetal demise at 13 0/7 to 16 0/7 weeks gestation/gestational size
4. Desiring uterine evacuation and signed procedure consent before signing study informed consent

5. BMI <40.0 kg/m²
6. English speakers and readers

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 years

Upper age limit

99 years

Sex

Female

Total final enrolment

0

Key exclusion criteria

1. Prior failed uterine evacuation attempt in the current pregnancy
2. Known cervical stenosis
3. Coagulopathy or current use of anticoagulants
4. Use of misoprostol within 48 hours prior to enrollment
5. Study staff or a member of the immediate family of a study staff
6. Any condition or circumstance that, in the opinion of the Investigator, would constitute contraindications to study participation, compromise the participant's ability to comply with the study protocol, or interfere with data collection

Date of first enrolment

12/05/2026

Date of final enrolment

30/09/2026

Locations**Countries of recruitment**

Canada

Sponsor information**Organisation**

Medicines360

ROR

<https://ror.org/02hfps373>

Funder(s)

Funder type

Funder Name

Medicines360

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available