

Vaginal misoprostol for first trimester termination of pregnancy prior to 9 weeks of gestation

Submission date 14/10/2002	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 14/10/2002	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 02/07/2009	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr CSW Ngai

Contact details

Department of Obstetrics and Gynaecology

Faculty of Medicine

University of Hong Kong

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Hong Kong

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Additional identifiers

Protocol serial number

831037

Study information

Scientific Title

Study objectives

Not provided at time of registration

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Medical abortion

Interventions

Patients will be randomised into two groups:

1. Group one will be treated using misoprostol with three drops of water (the 'water group')
2. Group two will only use misoprostol (the 'no water group')

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Misoprostol

Primary outcome(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

Completion date

01/01/2000

Eligibility**Key inclusion criteria**

1. The duration of menstrual delay is less than 49 days
2. The size of the uterus on pelvic examination is compatible with the estimated duration of pregnancy

3. A positive pregnancy test
4. There is no history of significant medical illness
5. Age greater than 16 years old
6. Requests legal termination of pregnancy

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

1. History or evidence of disorders that represent a contraindication to the use of misoprostol (mitral stenosis, glaucoma, sickle cell anaemia, diastolic pressure >100 mm Hg, bronchial asthma)
2. History or evidence of thrombo-embolism, severe or recurrent liver disease or pruritus of pregnancy
3. Presence of intrauterine contraceptive device (IUCD) in utero
4. Suspect or proven ectopic pregnancy
5. Heavy smoker (smoking >10 cigarettes daily in the past 2 years) or had another risk factor for cardiovascular disease

Date of first enrolment

01/01/1998

Date of final enrolment

01/01/2000

Locations**Countries of recruitment**

Hong Kong

Study participating centre

Department of Obstetrics and Gynaecology

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Hong Kong

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Sponsor information

Organisation

Hong Kong Health Services Research Fund (Hong Kong)

ROR

<https://ror.org/03qh32912>

Funder(s)

Funder type

Government

Funder Name

Hong Kong Health Services Research Fund (Hong Kong)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2000		Yes	No