ISRCTN18011364 https://doi.org/10.1186/ISRCTN18011364

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

Submission date
14/10/2002

Recruitment status
No longer recruiting

Registration date
14/10/2002

Overall study status
Completed

Last Edited
02/07/2009

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Contact details
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University of Hong Kong
-
Hong Kong
-

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/1998

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

Age group
Adult

Sex
Female

Target number of participants
80

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
-
Hong Kong
-

Sponsor information

Organisation
Hong Kong Health Services Research Fund (Hong Kong)

Sponsor details
Health Welfare and Food Bureau
Government Secretariat, HKSAR
20th floor Murray Building
Garden Road
-
Hong Kong
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+852 (0)2973 8288
hsrf@hwfb.gov.hk

Sponsor type
Government

Website
http://www.fhb.gov.hk/grants/english/funds/funds_hhsrf/funds_hhsrf_abt/funds_hhsrf_abt.html

ROR
https://ror.org/03qh32912

Funder(s)

Funder type
Government

Funder Name
Hong Kong Health Services Research Fund (Hong Kong)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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