

Second trimester termination of pregnancy, outcome after one or two day mifepristone-misoprostol interval

Submission date 13/10/2008	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 16/01/2009	Overall study status Completed	☐ Protocol
Last Edited 04/01/2013	Condition category Pregnancy and Childbirth	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

0902

Study information

Scientific Title

Second trimester termination of pregnancy, outcome after one or two day mifepristone-misoprostol interval: a randomised controlled trial

Study objectives

The combined regimen of mifepristone and misoprostol can be used at one day or two day interval without losing effectiveness.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of the Helsinki University Hospital, Department of Obstetrics and Gynaecology, approved on 01/10/2007 (ref: HUS 244/E9/07)

Primary study design

Interventional

Study design

Randomised controlled single-centre trial

Study type(s)

Other

Health condition(s) or problem(s) studied

Termination of second trimester pregnancy

Interventions

The study is a prospective, randomised, single-centre study of about 150 patients seeking a second trimester termination of pregnancy at Helsinki University Hospital during 01/06/2008-31/06/2009.

The participating patients will be randomised into two groups, having misoprostol (vaginally, or orally in cases of heavy uterine bleeding) either 20-28 or 40-48 hours after mifepristone (oral). The dose of mifepristone is single (200 mg) and misoprostol 0.4 mg doses will be given in 3-4 hours interval up to 5 times, until the abortion occurs.

The patients will have a check-up after 2-4 weeks.

Intervention Type

Drug

Phase

Phase IV

Drug/device/biological/vaccine name(s)

Mifepristone, misoprostol

Primary outcome(s)

1. Time to termination of pregnancy
2. Need for surgical curettage

Key secondary outcome(s)

No secondary outcome measures

Completion date

30/06/2009

Eligibility

Key inclusion criteria

1. Age over 18 years
2. Duration of pregnancy (as verified by ultrasonography) between 12 weeks (12+1) up to 24 weeks (24+0) and approval for termination from the Finnish National Authority for Medico-legal Affairs (TEO)
3. Singleton, live pregnancy
4. Voluntary participation and signed approval to the study
5. No intrauterine device (IUD) in utero at the time of abortion

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

Female

Key exclusion criteria

1. Allergy to mifepristone or misoprostol
2. Severe, complicated asthma
3. An extrauterine pregnancy
4. No common language with the investigators
5. A coronary disease or high risk factors for it
6. HIV or hepatitis (a smaller group having blood samples taken)

Date of first enrolment

01/06/2008

Date of final enrolment

30/06/2009

Locations

Countries of recruitment

Finland

Study participating centre
Helsinki University Central Hospital (HUCH)
Helsinki
Finland
00029 HUS

Sponsor information

Organisation
Helsinki University Hospital (Finland)

ROR
<https://ror.org/02e8hzf44>

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Helsinki University Hospital (Finland)

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	01/08/2012		Yes	No