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

Submission date
13/10/2008

Recruitment status
No longer recruiting

Registration date
16/01/2009

Overall study status
Completed

Last Edited
04/01/2013

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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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)

Study design
Randomised controlled single-centre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet (in Finnish and Swedish)

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

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/06/2008

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

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
Approximately 150-200

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)

Sponsor details
c/o Dr Oskari Heikinheimo
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00029 HUS

Sponsor type
Hospital/treatment centre

Website
http://www.hus.fi/

ROR
https://ror.org/02e8hzf44

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Helsinki University Hospital (Finland)

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	01/08/2012		Yes	No