ISRCTN35300716 https://doi.org/10.1186/ISRCTN35300716

A comparative pharmacokinetic study of oral mifepristone and vaginal misoprostol in pregnant women

Submission date 15/05/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 15/05/2008	**Overall study status** Completed	
Last Edited 15/05/2008	**Condition category** Pregnancy and Childbirth	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Helena von Hertzen

Contact details
World Health Organization (WHO)
20 Avenue Appia
Geneva-27
Switzerland
CH-1211
+41 (0)22 791 3376
vonhertzenh@who.int

Additional identifiers

Protocol serial number
A65037

Study information

Scientific Title

Study objectives
The present study aims at comparing the pharmacokinetics of the original formulations of mifepristone and misoprostol and a new generic co-packaged product. This is necessary to demonstrate bioequivalence to regulatory authorities.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from:
1. World Health Organization (WHO) Scientific and Ethical Review Group, Department of Reproductive Health and Research on the 27th April 2006 (ref: A65037)
2. Ethics Committee of Gynaecology and Obstetrics, Otology, Ophtalmology, Neurology and Neurosurgery of the Hospital District of Helsinki and Uusimaa on the 17th August 2006 (ref: 297 /E9/06)
3. WHO Ethics Review Committee on the 13th September 2007 (ref: A65037)

Study design
Randomised single-blind study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Pregnancy

Interventions
To demonstrate bioequivalence a new generic co-packaged mifepristone (one tablet x 200 mg) /misoprostol (four tablets x 0.2 mg) product (SunPharma, India) with the original formulations of mifepristone (one tablet x 200 mg [Exelgyn, France]) and misoprostol (four tablets x 0.2 mg [Pfizer, USA]).

Contact details for Principal Investigator:
Dr Oskari Heikinheimo
Department of Obstetrics and Gynaecology
Helsinki University Central Hospital
Helsinki
00029-HUS
Finland
Tel: +358 (0)40 587 1070
Fax: +358 (0)94 717 4801
Email: oskari.heikinheimo@helsinki.fi

Details of joint sponsor:
Concept Foundation (Thailand)
111 Paholyothin Rd
Thailand Science Park
Pathumthani

12120
Thailand
Tel: +66 (0)2 564 8021
Fax: +66 (0)2 564 8024
Email: phall@rhalliance.org
Website: http://www.conceptfoundation.org

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Mifepristone, misoprostol

Primary outcome(s)
The primary outcome of the study will be to ascertain the bioequivalence of each the two formulations of mifepristone and misoprostol, as determined by the measurement of the pharmacokinetic parameters, maximum serum concentration (Cmax), time to maximum serum concentration (tmax) and area under the curve (AUC) in each study group.

Key secondary outcome(s))
The secondary outcome will be the efficacy (defined as the proportion of complete abortions in each study group) and side effects of each of the two product regimens. The complete abortion rate and the induction to abortion interval will also be compared. Adverse events, if any, will be analysed on an intention to treat basis.

Completion date
19/10/2008

Eligibility

Key inclusion criteria
Subjects admitted to the study will fulfil the following criteria:
1. Good general health
2. Older than the legal age of consent
3. On day one of the study (day of mifepristone administration) the duration of pregnancy is not more than 63 days (counted from the first day of the last menstrual period) in a normal 28-day cycle
4. The duration of the pregnancy corresponds to the length of amenorrhoea when verified by ultrasound; if the gestational length according to ultrasound measurements differ by more than four days, the ultrasound dating will be used
5. The pregnancy is single and intrauterine (single sac)
6. If treatment with misoprostol should fail, subject agrees to surgical termination of pregnancy
7. Willing and able to participate in the study once the objective and study requirements have been explained

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
Subjects will not be recruited if any of the following conditions are present:
1. Allergy towards mifepristone or misoprostol
2. A history or evidence of disorders that represent a contraindication to the use of mifepristone (chronic adrenal failure, severe asthma uncontrolled by corticosteroid therapy, inherited porphyria)
3. A history or evidence of disorders that represent a contraindication to the use of prostaglandins (mitral stenosis, glaucoma, sickle cell anaemia, diastolic pressure over 90 mmHg, bronchial asthma, arterial hypotension)
4. A history or evidence of thrombo-embolism, severe or recurrent liver disease or pruritus of pregnancy
5. Has any medical condition or disease that requires regular treatment with systemic drugs, care or precaution in conjunction with abortion
6. Tendency of abnormal bleeding (such as von Willebrandt's disease)
7. The presence of intrauterine device (IUD) in utero
8. Previous surgery of uterus/uterine cervix is a relative contraindication, however, previous low-segment caesarean section is not a contraindication
9. Suspicion of any pathology of pregnancy (e.g., molar, non-viable pregnancy, threatened abortion)
10. Suspected or known breast or genital neoplasia
11. Breast-feeding
12. Where difficulties are anticipated in follow-up

Date of first enrolment
19/10/2007

Date of final enrolment
19/10/2008

Locations

Countries of recruitment
Finland

Switzerland

Study participating centre

World Health Organization (WHO)
Geneva-27
Switzerland
CH-1211

Sponsor information

Organisation
World Health Organization (WHO) (Switzerland)

ROR
https://ror.org/01f80g185

Funder(s)

Funder type
Research organisation

Funder Name
World Health Organization (WHO) (Switzerland) (ref: A65037)

Alternative Name(s)
, , Всемирная организация здравоохранения, Organisation mondiale de la Santé, Organización Mundial de la Salud, WHO, , ВОЗ, OMS

Funding Body Type
Government organisation

Funding Body Subtype
International organizations

Location
Switzerland

Funder Name
Concept Foundation (Thailand) (ref: BE0101)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary