

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

Submission date 15/05/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 15/05/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 15/05/2008	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

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

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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]).

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Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Mifepristone, misoprostol

Primary outcome measure

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 (C_{max}), time to maximum serum concentration (t_{max}) and area under the curve (AUC) in each study group.

Secondary outcome measures

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.

Overall study start date

19/10/2007

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

Age group

Adult

Sex

Female

Target number of participants

60

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)

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Sponsor type

Research organisation

Website

<http://www.who.int>

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

Private sector organisation

Funding Body Subtype

International organizations

Location

Switzerland

Funder Name

Concept Foundation (Thailand) (ref: BE0101)

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