

A clinical study of gestrienone (R2323) in emergency contraception

Submission date 18/12/2009	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 04/01/2010	Overall study status Completed	☐ Statistical analysis plan
		☒ Results
Last Edited 29/03/2010	Condition category Pregnancy and Childbirth	☐ 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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Additional identifiers

Protocol serial number

WHO/HRP ID: A15022

Study information

Scientific Title

Gestrienone (R2323) in emergency contraception: a multicentre double blind randomised controlled trial

Study objectives

Compare two different types of antiprogestosterone for emergency contraception in four provinces in China.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. China: Institutional Review Board of National Research Institute for Family Planning approved on the 20th September 2005 (ref: A15022; Protocol: 95063)
2. WHO Secretariat Committee on Research Involving Human Subjects

All other centres will seek ethics approval before recruiting participants.

Primary study design

Interventional

Study design

Multicentre controlled randomised double-blind two-arm clinical trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Contraception

Interventions

1. 10 mg of gestrienone (R2323)
2. 10 mg of mifepristone (RU486)

Women were to receive a single dose of gestrienone or mifepristone within 72 hours after unprotected intercourse (initial visit). They were followed to 7 days after the expected first day of the participants' next menstrual period.

Intervention Type

Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)

Gestrienone (R2323), mifepristone

Primary outcome(s)

Pregnancy rates, measured at the follow up visit (7 days after expected next menstrual period) using urine pregnancy test and ultrasonography, if indicated.

Key secondary outcome(s)

1. Side effects, measured using daily diary cards which were given at the initial visit, and reviewed and recorded at the follow up visit
2. Timing of next menstrual period, measured using daily diary cards which were given at the initial visit and reviewed and recorded at the follow up visit

Completion date

28/02/2003

Eligibility

Key inclusion criteria

1. Requesting emergency contraception within 72 hour of unprotected intercourse
2. Only one act of unprotected intercourse during current cycle
3. Willing to abstain from further acts during current cycle
4. Regular menstrual cycles (24 to 42 days with no more than 5 days variation)
5. Having at least one spontaneous cycle before current cycle
6. Available for follow up in the next six weeks
7. Negative pregnancy test
8. Willing to participate
9. Aged 18 - 44 years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

Female

Key exclusion criteria

1. Pregnancy
2. Contraindication to mifepristone
3. Presence of chronic medical condition
4. Subfertility

Date of first enrolment

01/11/2002

Date of final enrolment

28/02/2003

Locations

Countries of recruitment

China

Study participating centre

National Research Institute for Family Planning

Beijing

China

100081

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)

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

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2010		Yes	No