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A clinical study of gestrienone (R2323) in emergency contraception

Submission date
18/12/2009

Recruitment status
No longer recruiting

Registration date
04/01/2010

Overall study status
Completed

Last Edited
29/03/2010

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

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 antiprogesterone 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.

Study design
Multicentre controlled randomised double-blind two-arm clinical trial

Primary study design
Interventional

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