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A clinical study of gestrienone (R2323) in emergency contraception

Submission date 18/12/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 04/01/2010	**Overall study status** Completed	
Last Edited 29/03/2010	**Condition category** Pregnancy and Childbirth	

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
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

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

Secondary outcome measures
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

Overall study start date
01/11/2002

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

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
800

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)

Sponsor details
20 Avenue Appia
Geneva
Switzerland
CH-1211

Sponsor type
Research organisation

Website
http://www.who.int/en/

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
Private sector organisation

Funding Body Subtype
International organizations

Location
Switzerland

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	01/04/2010		Yes	No