ISRCTN06428555 https://doi.org/10.1186/ISRCTN06428555

A prospective, randomised study to compare the effectiveness of the 24 hour versus 12 hour double doses regimen of levonorgestrel for emergency post-coital contraception

Submission date
23/03/2004

Recruitment status
No longer recruiting

Registration date
01/04/2004

Overall study status
Completed

Last Edited
31/05/2011

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
WHO/HRP ID 97137

Study information

Scientific Title

Study objectives
To compare the effectiveness of two double dose regimens of levonorgestrel (given at either 12 or 24 hour intervals) for emergency contraception. In addition, we studied the efficacy of both regimens when the coitus-treatment period was extended to 120 hours.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Institutional Review Board (IRB) approved the study at each participating centre

Study design
Multicentre controlled randomised 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

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

Interventions
1. Levonorgestrel two doses of 0.75 mg 12 hours apart
2. Levonorgestrel two doses of 0.75 mg 24 hours apart

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)

Levonorgestrel

Primary outcome measure
Pregnancy rate

Secondary outcome measures
1. Delay in onset of next menses
2. Incidence of side-effects

Overall study start date
01/10/1998

Completion date
01/06/2003

Eligibility

Key inclusion criteria
1. Requesting emergency contraception within 120 hours 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)
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. Not breastfeeding
10. No use of hormonal contraceptives or of rhythm or natural family planning method of contraception during current cycle
11. Not unsure about the date of last menstrual period

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
2071 at five centres (Hong Kong, Shanghai, Nanjing, Shenzhen and Beijing)

Key exclusion criteria
1. Post-abortion or post-partum patients whose period had not yet returned
2. Regular use of prescription drugs before admission to the study
3. Intercourse during the treatment cycle greater than 120 hours before admission into the study

Date of first enrolment
01/10/1998

Date of final enrolment
01/06/2003

Locations

Countries of recruitment
China

Hong Kong

Study participating centre
Department of Obstetrics and Gynaecology
-
Hong Kong
-

Sponsor information

Organisation
World Health Organisation (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 council

Funder Name

Hong Kong Research Grant Council (Hong Kong) (ref: HKU7286/98M)

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	01/01/2005		Yes	No