ISRCTN69287540 https://doi.org/10.1186/ISRCTN69287540

A randomised double-blind study to compare two regimens of Levonorgestrel in emergency contraception in Nigeria

Submission date 19/03/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 01/04/2004	**Overall study status** Completed	
Last Edited 09/02/2011	**Condition category** Pregnancy and Childbirth	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr D Chikamata

Contact details
World Health Organization
20 Avenue Appia
Geneva
Switzerland
CH-1211
chikamatad@who.int

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
WHO/HRP ID: A15062

Study information

Scientific Title

Study objectives
Compare two regimens of levonorgestrel for emergency contraception in seven centres in Nigeria.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration.

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

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

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 one dose of 1.5 mg

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Levonorgestrel

Primary outcome measure
Efficacy, side-effects and timing of next menstrual period at six weeks.

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/08/2002

Completion date
01/08/2004

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
3150 total, 450 per centre, 1575 per group

Key exclusion criteria
Does not comply with the above inclusion criteria.

Date of first enrolment
01/08/2002

Date of final enrolment
01/08/2004

Locations

Countries of recruitment

Nigeria

Switzerland

Study participating centre
World Health Organization
Geneva
Switzerland
CH-1211

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	01/10/2002		Yes	No
Results article	results	01/10/2010		Yes	No