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A clinical study of using copper intrauterine devices (IUDs) in emergency contraception

Submission date
14/01/2010

Recruitment status
No longer recruiting

Registration date
19/01/2010

Overall study status
Completed

Last Edited
19/01/2010

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

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
A15046/96506

Study information

Scientific Title
Copper intrauterine contraception for emergency contraception: a prospective multicentre study

Study objectives
The TCu380A IUD is highly effective as an emergency contraceptive.

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: A15046; Protocol: 96506)
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
Prospective multicentre efficacy trial

Study type(s)
Prevention

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

Interventions
Eligible participants requesting EC up to 120 hours after unprotected intercourse and desiring long-term contraception with IUD, were given TCu380A IUD and followed for 12 months, including follow-up visits 1 and 3 months after the IUD insertion.

Intervention Type
Device

Phase
Not Applicable

Primary outcome(s)
Efficacy of the TCu380A in parous and nulliparous Chinese women

Key secondary outcome(s)
1. Side effects of the TCu380A in parous and nulliparous Chinese women
2. Complications (such as upper genital tract infection) in the women who have IUD insertion for the purpose of emergency contraception
3. Continuation rate at one year of use

Completion date
15/01/2000

Eligibility

Key inclusion criteria
1. Requesting emergency contraception within 120 hour of unprotected intercourse
2. Regular menstrual cycles (24 to 42 days with no more than 5 days variation)

3. Having at least one spontaneous cycle before current cycle after recent discontinued hormonal contraception, abortion or delivery
4. Desire to use IUD as long term contraceptive
5. Available for follow up in one month, three months and 12 months
6. Negative pregnancy test
7. 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. Suspected or confirmed pregnancy
2. Any episode of pelvic inflammatory disease (PID) or pelvic abscess in the 12 months preceding trial admission
3. Sexually transmitted infection (STI) within the past six months
4. Any evidence of STI in clinical or laboratory examination during screening
5. Multiple sexual partners
6. Known or suspected genital tract malignancy
7. Cervical or uterine malformations
8. Vaginal bleeding of unknown aetiology
9. Multiple uterine fibroids associated with previous menstrual anomalies
10. Clinical or laboratory evidence of anaemia (haemoglobin less than 9 g/l)
11. Unsure about the date of their last menstrual period (LMP needed for pregnancy risk assessment)

Date of first enrolment
01/07/1997

Date of final enrolment
15/01/2000

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