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

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
14/01/2010	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
19/01/2010	Completed	Results
Last Edited	Condition category	Individual participant data
19/01/2010	Pregnancy and Childbirth	<ul><li>Record updated in last year</li></ul>

# Plain English summary of protocol

Not provided at time of registration

# Contact information

#### Type(s)

Scientific

#### Contact name

Dr Shangchun Wu

#### Contact details

National Research Institute for Family Planning 12 Da Hui Si, Hai Dian Qu Beijing China 100081

# 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.

#### Study design

Prospective multicentre efficacy trial

#### Primary study design

Interventional

#### 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, , BO3, 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?

Participant information sheet Participant information sheet 11/11/2025 No

Yes