

A randomised trial of interval insertion of the TCu380A and Levonorgestrel 20 mcg intrauterine device

Submission date 19/03/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 01/04/2004	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 11/08/2008	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

WHO/HRP ID 91908

Study information

Scientific Title

Study objectives

Compare the clinical performance of two Intrauterine Devices (IUD).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled 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

TCu380A versus 20 mcg Levonorgestrel releasing IUD (Mirena).

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Levonorgestrel

Primary outcome measure

1. Pregnancy rates at five years
2. Discontinuation reasons at five years
3. Overall continuation rates at five years

Secondary outcome measures

No secondary outcome measures

Overall study start date

01/12/1993

Completion date

01/07/1997

Eligibility**Key inclusion criteria**

1. Age less than 40 and more than 16 years
2. Had at least one pregnancy of at least 20 weeks gestation or a foetus delivered weighing more than 500 g
3. Willing to participate and rely solely on the IUD as method of fertility regulation
4. Frequently exposed to risk of pregnancy
5. Ability to attend follow-up visits

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

3800

Key exclusion criteria

1. History of recurrent pelvic inflammatory disease (PID)
2. Pelvic abscess
3. Episode of PID in 12 months prior to admission
4. Valvular heart disease
5. History of sexually transmitted infections in past six months
6. Undiagnosed genital tract bleeding
7. Current cervical or vaginal infection
8. Congenital malformation of vagina, cervix or uterus
9. Known or suspected genital tract or breast malignancy
10. Multiple uterine fibroids associated with previous menstrual abnormalities
11. Less than six weeks since parturition or termination of pregnancy
12. Lactation of less than six months duration
13. Active liver disease
14. History of thrombosis or thromboembolic disease
15. Clinical or laboratory evidence of anaemia
16. History of ectopic pregnancy or hydatiform mole grand mal epilepsy receiving medication

Date of first enrolment

01/12/1993

Date of final enrolment

01/07/1997

Locations

Countries of recruitment

Brazil

Chile

China

Hungary

Mongolia

Philippines

Slovenia

Switzerland

Thailand

Tunisia

Study participating centre

World Health Organization

Geneva

Switzerland

CH-1211

Sponsor information

Organisation

UNDP/UNFPA/WHO/World Bank - Special Programme of Research, Development and Research Training in Human Reproduction

Sponsor details

World Health Organization

20 Avenue Appia

Geneva

Switzerland

CH-1211

Sponsor type

Research organisation

Website

<http://www.who.int/reproductive-health/hrp/>

ROR

<https://ror.org/01f80g185>

Funder(s)

Funder type

Research organisation

Funder Name

United Nations Development Programme (UNDP)/United Nations Population Fund (UNFPA)
/World Health Organization (WHO)/World Bank - Special Programme of Research, Development
and Research Training in Human Reproduction (HRP)

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