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

Submission date	Recruitment status	[ ] Prospectively registered
19/03/2004	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
01/04/2004	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
11/08/2008	Pregnancy and Childbirth	[ ] 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

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