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Randomised controlled trial of two implantable contraceptives: Jadelle and Implanon

Submission date	Recruitment status	[_] Prospectively registered
22/03/2004	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
01/04/2004	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
18/10/2019	Pregnancy and Childbirth	

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 A15229

Study information

Scientific Title
Randomised controlled trial of two implantable contraceptives: Jadelle and Implanon

Study objectives
Prospective randomised trial to compare efficacy and acceptability of sub-dermal two contraceptive implants (Implanon and Jadelle) in women aged 18 to 44 year requesting long-term reversible contraception, plus a non-randomised comparison group of women using the TCu 380A copper intrauterine device. Women followed at six-monthly intervals up to three years since insertion.

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
Jadelle, Implanon, TCu380A (for the observational cohort).

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Pregnancies
2. Adverse events

3. Method continuation rates
4. Incidence of complaints reportedly associated with implant contraception
5. Vaginal bleeding patterns
Follow-up duration for primary endpoints: three years.

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/05/2003

Completion date
31/12/2008

Eligibility

Key inclusion criteria
1. General good health
2. Age between 18 and 44 years
3. Not pregnant
4. Requesting long-term reversible contraception
5. Able to keep a menstrual diary
6. Willing to return for follow-up

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
3000

Total final enrolment
2963

Key exclusion criteria
1. Breastfeeding an infant less than six weeks
2. High blood pressure
3. Current venous thromboembolism
4. Ischaemic heart disease
5. Vaginal bleeding
6. History of breast cancer

Date of first enrolment
01/05/2003

Date of final enrolment
31/12/2008

Locations

Countries of recruitment
Brazil

Chile

China

Dominican Republic

Hungary

Slovenia

Switzerland

Thailand

Türkiye

Zimbabwe

Study participating centre
World Health Organization
Geneva-27
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 Organisation
20 Avenue Appia

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Switzerland
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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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2015		Yes	No
Results article	results	01/09/2018	18/10/2019	Yes	No