

Randomised controlled trial of two implantable contraceptives: Jadelle and Implanon

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Tim Farley

Contact details
World Health Organization
20 Avenue Appia
Geneva-27
Switzerland
CH-1211
-
farleyt@who.int

Additional identifiers

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Contraception

Interventions

Jadelle, Implanon, TCU380A (for the observational cohort).

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

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.

Key secondary outcome(s)

No secondary outcome measures

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

Female

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

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

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