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Effects of vitamin E and low-dose aspirin, alone or in combination, on Norplant-induced prolonged bleeding

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	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
10/10/2014	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 96910

Study information

Scientific Title

Study objectives
To test the effectiveness and the acceptability of vitamin E and low-dose aspirin, alone or in combination, as treatment for prolonged vaginal bleeding induced by Norplant.

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)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Contraception

Interventions
Patients are randomised to one of four different 10-day oral treatments:
1. 200 mg vitamin E daily
2. 80 mg aspirin daily
3. Both of the above
4. Placebo

Intervention Type
Supplement

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Vitamin E, low-dose aspirin

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/2002

Completion date
01/01/2003

Eligibility

Key inclusion criteria
1. Women aged 18 - 38 years
2. 1 - 6 months post Norplant insertion
3. Non-lactating
4. Experiencing an episode of vaginal bleeding lasting more than 7 days

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
486

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/01/2002

Date of final enrolment
01/01/2003

Locations

Countries of recruitment
Chile

China

Dominican Republic

Indonesia

Switzerland

Tunisia

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
20, Avenue Appia
Geneva-27
Switzerland
CH 1211

Sponsor type
Research organisation

Website
http://www.who.int

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	01/12/2004		Yes	No