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 [] Statistical analysis plan Registration date Overall study status 01/04/2004 Completed [X] Results [] Individual participant data Last Edited Condition category 10/10/2014 Pregnancy and Childbirth

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

Protocol serial number 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

Study type(s)

Treatment

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(s)

Not provided at time of registration

Key secondary outcome(s))

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Female

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

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	01/12/2004		Yes	No