A study to determine whether a single hormone injection a month before insertion of the contraceptive implant will reduce or stop irregular vaginal bleeding

Submission date	Recruitment status	Prospectively registered
13/05/2008	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
07/08/2008	Completed	Results
Last Edited	Condition category	Individual participant data
09/05/2016	Urological and Genital Diseases	Record updated in last year

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 10467

Study information

Scientific Title

Irregular vaginal bleeding with etonorgestrel contraceptive implant: a pilot randomised controlled trial of prophylactic down regulation with a gonadotrophin releasing hormone analogue prior to implant insertion

Study objectives

Implanon® is the only progesterone-only sub-dermal contraceptive implant available in the United Kingdom (UK). It is independent of compliance, lasts for three years and has been shown to be effective, safe and easily reversible. UK data suggests almost two thirds of women who discontinue Implanon® do so for frequent or unpredictable bleeding, interventions to improve bleeding patterns are likely to have an effect of increasing continuation rates.

Gonadotrophin releasing hormone agonists (GnRHa) are a group of drugs with an agonist /antagonist action on the GnRH receptor in the pituitary gland. They induce down regulation of the pituitary resulting in blockage of gonadotrophin synthesis and secretion. GnRHa produce inhibition of pituitary function, follicular development, anovulation and a reversible hypogonadotrophic hypogonadism state which frequently induces amenorrhoea. What is uncertain is whether these effects are prolonged following the administration of progestagens.

It is therefore hypothesised that the amenorrhoea associated with down regulation by GnRHa one month prior to fitting Implanon® will persist after insertion, with a resultant high continuation rate and quality of life.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the Leicestershire, Northamptonshire and Rutland Research Ethics Committee 2 on the 1st May 2008 (ref: 08/H0402/3).

Study design

Single-centre, single-blind randomised placebo-controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Contraception, vaginal bleeding

Interventions

GnRH analogue and placebo:

- 1. Decapeptyl SR®, contains the active ingredient triptorelin acetate which is a gonadorelin analogue. The dose of the intramuscular injection is 11.25 mg, which is a sustained release preparation lasting for 90 days. It comes in a pre-filled syringe which will be supplied by the manufacturer in its standard form.
- 2. Placebo injection will consist of a 5 ml intramuscular injection of water for injection in its standard form

The treatment is a one off injection of either Decapeptyl SR or placebo and then a month later the implant is fitted and the women are followed up for one year (both treatment arms) so involvement for the women is 13 months.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Decapeptyl SR®

Primary outcome(s)

Mean number of bleeding and spotting days over each 90 day reference period for a total of one year from contraceptive implant insertion.

Key secondary outcome(s))

- 1. World Health Organisation (WHO) menstrual indices:
- 1.1. Number of vaginal bleeding and spotting episodes
- 1.2. Length of bleeding and spotting episodes
- 1.3. Length of bleeding and spotting free intervals
- 1.4. Range of bleeding and spotting free intervals
- 2. Continuation rates of the contraceptive implant at 12 months
- 3. Quality of life assessment with further 36-item Short Form health survey (SF-36) scores at 12 months

Completion date

31/12/2009

Eligibility

Key inclusion criteria

- 1. Women aged 20 40 years
- 2. Requesting Implanon® for contraception after appropriate counselling and consent
- 3. Willing to follow study protocol
- 4. Informed consent to participate in study

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

- 1. Contraindications to Implanon®:
- 1.1. Pregnancy
- 1.2. Undiagnosed vaginal bleeding
- 1.3. Severe arterial disease
- 1.4. Liver adenoma
- 1.5. Porphyria
- 1.6. Active gestational trophoblastic disease
- 1.7. Sex-steroid dependent cancer
- 1.8. Enzyme inducing medication
- 2. Contraindications to GnRHa:
- 2.1. Pregnancy
- 2.2. Undiagnosed vaginal bleeding
- 2.3. Breastfeeding
- 2.4. Metabolic bone disease
- 3. Unwilling to keep a regular menstrual diary
- 4. Unwilling to follow study protocol
- 5. Unable to understand patient information leaflet
- 6. Current involvement in other research projects
- 7. Within six weeks of termination of pregnancy

Date of first enrolment

01/07/2008

Date of final enrolment

31/12/2009

Locations

Countries of recruitment

United Kingdom

England

Study participating centre Contraceptive Services

Leicester United Kingdom LE2 0TA

Sponsor information

Organisation

University Hospitals of Leicester NHS Trust (UK)

ROR

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded (UK)

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?

Participant information sheet Participant information sheet 11/11/2025 11/11/2025 No Yes