

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

Primary study design

Interventional

Study design

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

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

<https://ror.org/02fha3693>

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