

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

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

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Dr Sharon Moses

### Contact details

Bristol Sexual Health Centre  
Tower Hill  
Bristol  
United Kingdom  
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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

## Secondary study design

Randomised controlled trial

## Study setting(s)

Not specified

## Study type(s)

Treatment

## Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

**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 measure**

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

**Secondary outcome measures**

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

**Overall study start date**

01/07/2008

**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

**Age group**

Adult

**Sex**

Female

**Target number of participants**

90

**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**

England

United Kingdom

**Study participating centre**  
**Contraceptive Services**  
Leicester  
United Kingdom  
LE2 0TA

## **Sponsor information**

**Organisation**  
University Hospitals of Leicester NHS Trust (UK)

**Sponsor details**  
c/o David Rowbotham  
Research Office  
Leicester General Hospital  
Gwendolen Road  
Leicester  
England  
United Kingdom  
LE5 4PW

**Sponsor type**  
Hospital/treatment centre

**Website**  
<http://www.uhl-tr.nhs.uk/>

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

## **Funder(s)**

**Funder type**  
Other

**Funder Name**  
Investigator initiated and funded (UK)

## **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