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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 [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 07/08/2008	**Overall study status** Completed	
Last Edited 09/05/2016	**Condition category** Urological and Genital Diseases	

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
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