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A pilot study to assess the feasibility of a RCT to compare the effectiveness of two different progesterone only pills (POP) on reducing pelvic pain

Submission date
30/09/2004

Recruitment status
No longer recruiting

Registration date
30/09/2004

Overall study status
Completed

Last Edited
11/07/2016

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0530128908

Study information

Scientific Title
A pilot study to assess the feasibility of a RCT to compare the effectiveness of two different progesterone only pills (POP) on reducing pelvic pain

Study objectives
This pilot study aims to assess if data collected supports the theoretical superiority of Cerazette over Femulen in reducing cyclical pelvic pain. It also aims to assess the feasibility of conducting a larger trial in the future.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled pilot study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Urological and Genital Diseases: Pelvic pain

Interventions
Comparison of two different progesterone only pills, Cerazette and Femulen

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)

Cerazette, Femulen

Primary outcome measure
If Cerazette is effective in reducing the pain associated with ovulation and menstruation, it will provide a valuable alternative choice for women who are unable to chose not to take combined oral contraceptives (COCs).

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/03/2003

Completion date
30/03/2004

Eligibility

Key inclusion criteria
1. Females over 18 years of age who require a method of contraception
2. Willing to follow protocol
3. Able to give written consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
25

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/03/2003

Date of final enrolment
30/03/2004

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Margaret Pyke Centre
London
United Kingdom
W1T 4PL

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
North Central London Research Consortium (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