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	Recruitment status	Prospectively registered
30/09/2004	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
30/09/2004	Completed	Results
Last Edited	Condition category	Individual participant data
11/07/2016	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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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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).

Key secondary outcome(s))

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Female

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

United Kingdom

England

Study participating centre Margaret Pyke Centre

London United Kingdom W1T 4PL

Sponsor information

Organisation

Department of Health

Funder(s)

Funder type

Government

Funder Name

North Central London Research Consortium (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration