

# 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

<b>Submission date</b> 30/09/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 30/09/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 11/07/2016	<b>Condition category</b> 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 Jo Power

### Contact details

Margaret Pyke Centre  
73 Charlotte Street  
London  
United Kingdom  
W1T 4PL  
+44 (0)20 7 530 3640  
jopower1@hotmail.com

## 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