

# Does topical anaesthetic gel reduce pain /discomfort during intrauterine device (IUD) /intrauterine system (IUS) insertion? A randomised, placebo-controlled, double-blind trial

<b>Submission date</b> 25/07/2008	<b>Recruitment status</b> Stopped	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 21/08/2008	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 20/11/2012	<b>Condition category</b> Pregnancy and Childbirth	<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**  
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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

MPC 135

## **Study information**

### **Scientific Title**

Does topical anaesthetic gel (Instillagel®) reduce pain discomfort during insertion of intrauterine contraception? A randomised, placebo-controlled, double-blind trial

### **Study objectives**

Intrauterine device (IUD)/intrauterine system (IUS) are highly effective, long-acting, reversible methods of contraception, and increasing uptake of these methods among women in the UK and elsewhere will reduce unintended pregnancies. Fear or experience of pain during insertion constitute an important barrier to uptake of these methods. Reliable evidence about reducing pain or discomfort during insertion is essential to:

1. Improve the experience for women having an IUD/IUS fitted and advise them appropriately
2. Provide more evidence based guidelines for health care professionals in IUD/IUS insertion

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

To be submitted as of 25/07/2008

### **Study design**

Single-centre, randomised, placebo-controlled, double-blind trial

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Not specified

### **Study type(s)**

Not Specified

### **Participant information sheet**

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

### **Health condition(s) or problem(s) studied**

Unintended pregnancy and abortion

### **Interventions**

2% lignocaine gel (Instillagel®; topical) or an inert equivalent of it will be provided by the manufacturer of Instillagel®. This will be coded and the code only released at the end of the trial. Neither the woman, or the clinician (nor statistician) will be aware of the active/placebo status.

Please use the following contact details to request a patient information sheet:

Miss Heidi Chandler  
Study Co-ordinator  
University College London (UCL)  
Research Unit  
Margaret Pyke Centre  
73 Charlotte Street  
London, W1T 4PL  
United Kingdom  
Email: hchandler@gum.ucl.ac.uk

Please note that this trial was stopped in March 2009.

### **Intervention Type**

Drug

### **Phase**

Not Specified

### **Drug/device/biological/vaccine name(s)**

lignocaine (Instillagel®)

### **Primary outcome measure**

Pain scores at the end of the insertion procedure. Pain scores will be assessed visually using a numerical rating scale of 1-10.

### **Secondary outcome measures**

Pain scores relating to the use of the Allis forceps prior to IUD/IUS insertion. Pain scores will be assessed visually using a numerical rating scale of 1-10.

### **Overall study start date**

01/09/2008

### **Completion date**

28/02/2010

### **Reason abandoned (if study stopped)**

Lack of funding/scholarship

## **Eligibility**

### **Key inclusion criteria**

1. Women choosing an IUD/IUS, for whom this is an appropriate choice of contraception
2. Between the ages of 16 and 45

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Female

**Target number of participants**

200

**Key exclusion criteria**

Women choosing an IUD/IUS, for whom this is not an appropriate choice of contraception

**Date of first enrolment**

01/09/2008

**Date of final enrolment**

28/02/2010

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre****Research Unit**

London

United Kingdom

W1T 4PL

**Sponsor information****Organisation**

Camden NHS Primary Care Trust (UK)

**Sponsor details**

Research & Development Department

Research Unit

3rd Floor West Wing

St Pancras Hospital

St Pancras Way

London  
England  
United Kingdom  
NW1 0PE  
+44 (0)20 7530 5375  
angela.williams@camdenpct.nhs.uk

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.camdenpct.nhs.uk>

## **Funder(s)**

**Funder type**

Charity

**Funder Name**

The Moulton Charitable Foundation (UK)

**Funder Name**

CliniMed (UK) (provides Instillagel® and placebo)

## **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