

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

Submission date 25/07/2008	Recruitment status Stopped	☒ Prospectively registered
		☐ Protocol
Registration date 21/08/2008	Overall study status Stopped	☐ Statistical analysis plan
		☐ Results
Last Edited 20/11/2012	Condition category Pregnancy and Childbirth	☐ 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

Protocol serial number
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

Study type(s)

Not Specified

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

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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(s)

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

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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

United Kingdom

England

Study participating centre

Research Unit

London

United Kingdom

W1T 4PL

Sponsor information

Organisation

Camden NHS Primary Care Trust (UK)

Funder(s)

Funder type

Charity

Funder Name

The Moulton Charitable Foundation (UK)

Funder Name

CliniMed (UK) (provides Instillagel® and placebo)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

