ISRCTN83819888 https://doi.org/10.1186/ISRCTN83819888

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	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 21/08/2008	**Overall study status** Stopped	
Last Edited 20/11/2012	**Condition category** Pregnancy and Childbirth	

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

Primary study design
Interventional

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

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:
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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