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A study to investigate a tailor-made device designed to insert an intrauterine contraceptive device (IUD) immediately after childbirth

Submission date
03/03/2026

Recruitment status
Recruiting

Registration date
10/03/2026

Overall study status
Ongoing

Last Edited
02/06/2026

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
An intrauterine device (IUD) – sometimes also known as a 'coil' – is a popular method of contraception. It is a small T-shaped device about the size of a 50 pence coin. It is available in hormonal and non-hormonal (copper) types. The IUD is inserted into the womb by a healthcare professional during a short procedure. This procedure usually involves passing a thin plastic straw containing the IUD through the entrance to the womb (cervix). The plastic insertion tube is then removed leaving the IUD inside the womb.
It is also possible to insert an IUD right after a baby is born. This is known as postpartum intrauterine device insertion, or PPIUD. Previous research has shown that it is very safe to have an IUD inserted at this time. It is often easier and maybe less painful to insert an IUD as the cervix is already wide open to allow the baby to be born. As the womb is larger after birth than it is at any other time, we need to use a different technique to insert a postpartum IUD. The regular plastic IUD insertion tube is not long enough to reach the top of the womb at this time. Therefore, the IUD is usually placed inside the womb using metal 'tongs' or forceps.
This study will investigate a plastic 'straw' device designed to insert the IUD immediately after normal childbirth (or within 48 hours). It has been made especially for inserting an IUD after birth, which is large enough to reach the top of the womb. This means that it can fit the size and shape of the womb better after birth. This inserter might make the procedure simpler to perform and more comfortable for women than the current method (forceps). If successful, the plastic inserter could help make the IUD a more available contraceptive option for women after childbirth.

Who can participate?
Women who are pregnant and intend on a vaginal birth and wish to receive an intrauterine device (hormonal or non-hormonal) for contraception within the first 48 hours after birth.

What does the study involve?
During pregnancy participants will consent and be randomised to either the investigational device or the standard insertion technique. Shortly after the baby is born one of the midwives or doctors will attend to insert the IUD as per randomisation allocation. During the insertion,

participants will be asked to complete a brief pain questionnaire immediately before and after the IUD is fitted (this involves selecting a score on a chart) and a short satisfaction survey. 6 weeks postpartum participants will be asked to attend an in-person follow-up. This will include an ultrasound scan to check the position of the IUD inside the womb, a gentle examination using a speculum (a plastic device that is placed in the vagina and opened to be able to view the cervix) to check for the IUD threads and trim them if necessary and some questions about symptoms, infant feeding and resumption of sex. At 12 weeks postpartum, participants will be followed up again via telephone. They will be asked some questions about symptoms, infant feeding and resumption of sex. This is the last activity they will be involved in during the research study.

What are the possible benefits and risks of participating?
By taking part in this study, we will arrange the follow-up IUD thread check-up with the research team at a time that is convenient for the participant. This appointment will take place in a specialist clinic and replace the standard check-up at a GP practice. We will be able to perform all the usual checks and an ultrasound scan at the same visit. This might mean fewer appointments and a shorter waiting time. Otherwise, there are no direct benefits to the participant taking part, but the results might help to improve the healthcare of patients in the future.
No additional risks have been identified whether the IUD is fitted with the plastic inserter or metal tongs. Known risks of IUD insertion are similar whether the IUD is inserted at the time of birth or not. IUD insertion risks include infection (1 in every 100 people), uterine perforation (1-2 in every 1000 people), device expulsion (1 in every 20 people), pain (variable from person to person) and unusual menstrual bleeding or cramping. There are some extra steps and time that will be required. These include:
1. Screening/consent appointment (up to 30 minutes)
2. Brief questionnaire about pain at the time the IUD is inserted (5 minutes)
3. Follow-up visit at the research clinic instead of GP practice – up to 1 hour
4. Telephone questionnaire – up to 20 minutes

Where is the study run from?
The study will take place in NHS Lothian. The research team is based at NHS Lothian and the University of Edinburgh (UK)

When is the study starting and how long is it expected to run for?
May 2026 to February 2027

Who is funding the study?
The study is funded by the Chief Scientist Office and the Edinburgh Family Planning Trust (UK)

Who is the main contact?
Karen McCabe (research midwife) on 07973 760871 or chalmers.research@ed.ac.uk

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Integrated Research Application System (IRAS)
350561

Central Portfolio Management System (CPMS)
72215

Study information

Scientific Title
Use of a dedicated insertion device for immediate postpartum intrauterine contraception provision: a feasibility randomised controlled trial (POP-IN)

Acronym
POP-IN

Study objectives
1. To assess the feasibility of a definitive trial in terms of recruitment, retention and adherence.
2. To determine the ease and acceptability of insertion from patientS' and providers' perspectives of the inserter for postpartum IUD placement compared to the forceps (standard care)

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 14/10/2025, North West - Greater Manchester South Research Ethics Committee (2 Redman Place Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8014; gmsouth.rec@hra.nhs.uk), ref: 25/NW/0226

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Single

Purpose
Device feasibility

Study type(s)

Health condition(s) or problem(s) studied
Contraception

Interventions
The device under investigation is a postpartum IUD (PPIUD), which consists of a dedicated postpartum inserter and a pre-loaded (copper) CU-IUD. The postpartum inserter is a long tube of plastic, which is a longer, wider version of some of the standard (non-postpartum) IUD inserters

in use in the UK which better accommodates the anatomy of the womb immediately post-birth. The main aim of this study is to assess the feasibility of running a study, which will demonstrate the safety and efficacy of this PPIUD inserter compared to the current technique (long metal forceps). The target population are individuals who are within 48 hours of a vaginal birth and who wish to receive immediate postpartum insertion of a hormonal or copper IUD for ongoing contraception.

Participants will be randomised in a 3:1 allocation to the investigational device or standard insertion technique, based on single-sequence random assignment. This will be achieved using bespoke web-based randomisation software provided and maintained by the Edinburgh Clinical Trials Unit (ECTU). Randomisation will take place after informed consent and screening eligibility have been confirmed, prior to childbirth. Participants will be randomised to receive their choice of IUD (hormonal or copper) using either the investigational device (n = 90) or through the standard insertion technique using metal forceps (n = 30). In both cases, the IUD itself will remain inside the uterus, but the insertion device (plastic tube or forceps) is removed immediately after placing the IUD.

Two study visits will take place at 6 and 12 weeks following IUD insertion to gather study data. Week 6 follow-up will be in-person, and the week 12 follow-up will be conducted by telephone. The total duration of participant involvement will depend on when they are recruited during pregnancy but is expected to be a minimum of 3 months and a maximum of 9 months.

Intervention Type
Device

Phase
Phase II

Drug/device/biological/vaccine name(s)
PPIUD Cu T 380A

Primary outcome(s)
1. The feasibility of a definitive trial in terms of recruitment measured using the proportion of screened participants who are initially eligible, consented, randomised, confirmed eligible post birth and those who had an IUD inserted, at screening, consent, randomisation and at day 0 (day of insertion)

2. The feasibility of a definitive trial in terms of retention measured using the retention of participants as a proportion of those receiving intervention at 6 and 12 weeks postpartum

3. The feasibility of a definitive trial in terms of adherence measured using protocol adherence (frequency, proportion and nature of protocol deviations) at throughout the trial

4. The acceptability of insertion from patient perspective of the inserter for postpartum IUD placement compared to the forceps (standard care) measured using participant-rated pain during insertion on a 10 cm visual analogue scale at immediately prior to, during and after the insertion procedure

5. The ease of insertion from providers' perspective of the inserter for postpartum IUD placement compared to the forceps (standard care), measured using provider-rated ease of insertion on a 5-point Likert scale at immediately after insertion procedure

Key secondary outcome(s))
1. Complications: infection and uterine perforation measured using adverse event reporting at Day 0, 6 and 12 weeks postpartum

2. Accuracy of the IUD placement and presence/absence of IUD rotation measured using transvaginal pelvic ultrasound at 6 weeks post-insertion (and after insertion if available)

3. IUD expulsion and continuation rates measured using observations by staff or participants at 6 and 12 weeks

4. Patient satisfaction with the insertion procedure measured using 5-point Likert scale at Day 0 and 6 weeks

5. Alternative contraception methods used if the IUD is not in place and pregnancy status measured using self report at 6 and 12 week postpartum

Completion date
28/02/2027

Eligibility

Key inclusion criteria
1. Age 16 years or over
2. Currently pregnant
3. Intending a vaginal birth
4. Wishing to receive an intrauterine device (hormonal or non-hormonal) for contraception within the first 48 hours after birth
5. Suitable to have an IUD for contraception
6. Fluent in written/spoken English
7. Capacity to provide informed consent
8. Willingness to be randomised to investigational device

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
16 years

Upper age limit
70 years

Sex
Female

Total final enrolment
0

Key exclusion criteria
1. Abnormal uterine anatomy e.g. large fibroids, Mullerian malformation
2. Pre-existing conditions that are in category 3 or 4 of the UK Medical Eligibility Criteria for use of IUD
3. Non-vaginal birth, e.g. unplanned or emergency Caesarean-section
4. Suspected or confirmed pelvic or intrauterine infection or systemic sepsis at time of insertion
5. Prolonged rupture of membranes (>36 hours between ROM and delivery*) prior to insertion
6. Unresolved postpartum haemorrhage
7. No longer consenting to take part in the trial, i.e. willing to have their chosen IUD inserted as part of the trial post childbirth

Date of first enrolment
27/05/2026

Date of final enrolment
30/11/2026

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
NHS Lothian
Waverley Gate
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Sponsor information

Organisation
Accord (United Kingdom)

ROR
https://ror.org/01x6s1m65

Funder(s)

Funder type

Funder Name
Chief Scientist Office, Scottish Government Health and Social Care Directorate

Alternative Name(s)
Chief Scientist Office, Scottish Government Health Directorate CSO, Chief Scientist Office, Scottish Government Health Directorates, Chief Scientist Office of the Scottish Government Health Directorates, Scottish Government Health and Social Care Directorate of the Chief Scientist Office, Scottish Government Health Directorate Chief Scientist Office, The Chief Scientist Office, CSO

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Edinburgh Family Planning Trust

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the study will be available upon request from Sharon Cameron (Sharon.Cameron@ed.ac.uk)

IPD sharing plan summary
Available on request