Participant Information Sheet

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

You are invited to take part in a research study. To help you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish. Contact us if there is anything that is not clear, or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

Background to the study

An intrauterine device (or 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 (containing 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 (see below).

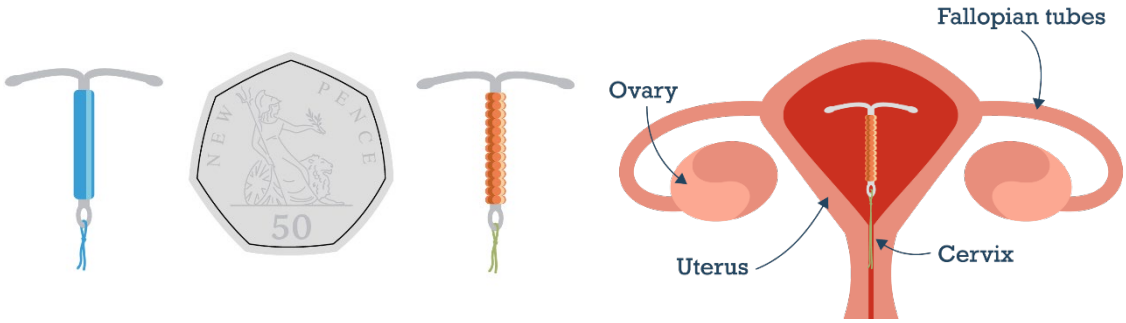
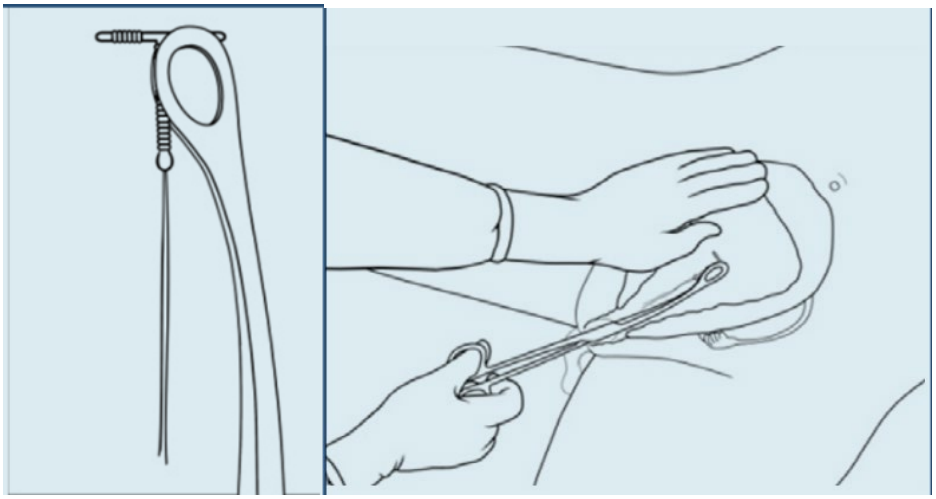


Image on left shows size of the hormonal (left, blue colour) and non-hormonal (right, orange colour) copper IUD compared to 50 pence coin. Image on the right shows IUD inside the womb.

It is also possible to insert an IUD right after your baby is born. This is known as postpartum intrauterine device insertion, or PPIUD for short. Previous research has shown that it is very safe to have an IUD inserted at this time. It is often easier and may be less painful to insert an IUD as the cervix is already wide open to allow the baby to be born. It can also save having to attend an appointment a few weeks after birth to have the IUD fitted. Research has shown that there is a slightly higher chance of an IUD falling out if it is inserted shortly after birth. This service has been available to patients in Lothian since 2016, but it is considered "off license" use of the IUDs because they were originally designed to be inserted from 6 weeks after birth.

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 thin metal 'tongs' or forceps.



Images showing the metal 'tongs' (or forceps) used to insert an IUD into the womb shortly after birth

However, a new plastic insertion tube 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 new inserter has been approved for use by the World Health Organisation. It has already been tested in several countries outside of Europe, including in India and Africa. This will be the first research study to test this PPIUD inserter in the UK.

The plastic PPIUD insertion tube comes pre-packaged with a copper IUD, just like a regular IUD insertion tube. The copper IUD can be removed and replaced with a hormonal IUD if this method is preferred. Whether you choose to have a copper or hormonal IUD will not affect your follow-up assessments or care.

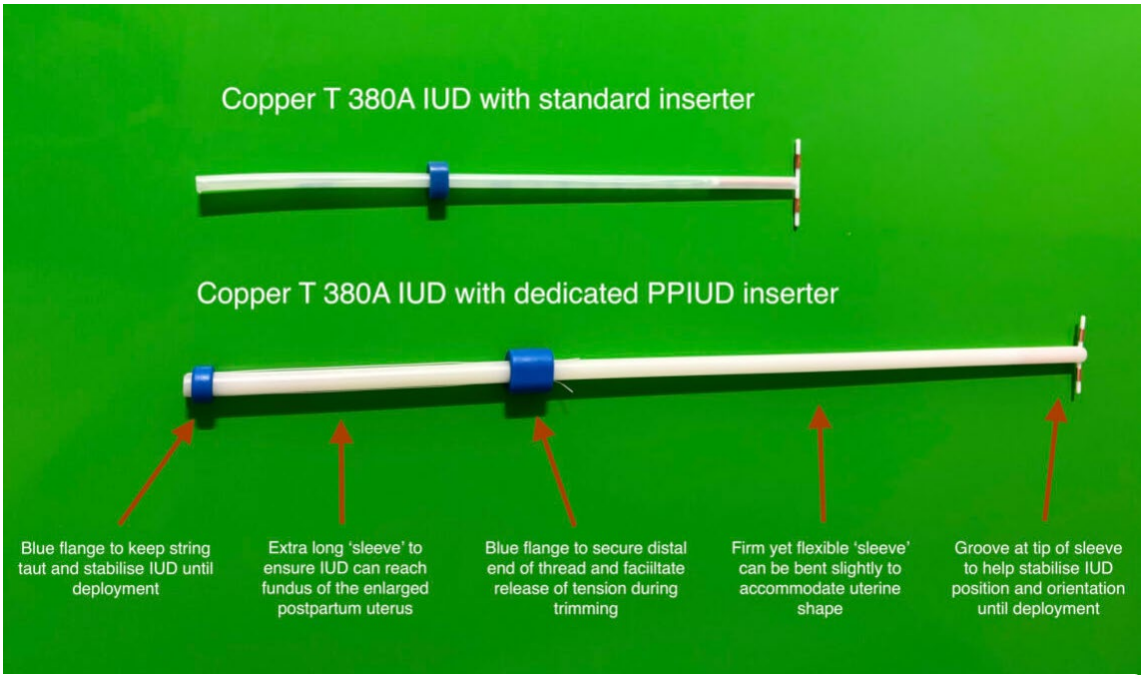


Image showing the postpartum intrauterine device (PPIUD) plastic inserter (bottom) compared to the usual inserter used to insert an IUD into a non-pregnant womb (top)

Why is the study being conducted?

This study will investigate this new plastic inserter for inserting an IUD after birth. We want to know if the inserter might make the procedure even easier to perform and even more comfortable for patients than the current standard technique (metal 'tongs'). If the study is successful, the plastic inserter could become available to use in the NHS. This could help to make the IUD a more easily available contraceptive option for women after childbirth.

What are you trying to achieve?

In this study the plastic inserter will be compared to the metal 'tongs'. Anyone who wishes to have an IUD (copper or hormonal) after a vaginal birth can participate in the study. We plan to invite 120 people to take part. We will divide the group into two, one group will receive their IUD using the standard technique (tongs) and the other group will receive their IUD using the new technique (plastic inserter). To compare the two techniques fairly they need to be the same ensuring that differences in results between the two groups are solely due to the technique and not to other factors. To try to make the two groups the same, each person is put into a group randomly, this is called randomisation. No one will be able to decide which technique is used. There will be 90 people in the group receiving their IUD with the new technique and 30 people in the group receiving their IUD using the standard technique. This means that you are three times more likely to receive the IUD using the new technique (plastic inserter) than with the standard technique (metal tongs). IUD insertion will be performed by doctors or midwives immediately after birth, irrespective of which technique is being used.

For the two groups (tongs and plastic inserter) we will compare the numbers with the IUD in the correct position, how easy it was to insert, patient experience of comfort/discomfort with the insertion, any complications, and the number of people with the IUD still in place 6 and 12 weeks later.

Why have I been invited to take part?

You have been asked to take part because you are currently pregnant and might be interested to receive an IUD for contraception.

Do I have to take part?

No, it is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. Deciding not to take part or withdrawing from the study will not affect the healthcare that you receive, or your legal rights.

What will happen if I take part?

Your antenatal midwife or doctor will provide information on the study (a flyer and this information sheet) if you wish to receive PPIUD. They will also ask your permission to share your contact details so the one of the research team midwifes can contact you. The research midwife will discuss with you in more detail about what the study involves, check you are suitable to take part and answer any questions you may have. This can be over the phone or in person, as you prefer.

You can take as much time as you need to decide whether to take part in the study. If you are still happy to take part, a member of the research team will ask you to sign a consent form. You will be asked some questions, for example about your general health and previous pregnancies. They can also answer questions to help you decide between the hormonal or copper IUD. This will be face to face at a convenient time and location for you – this may include before or after a routine antenatal appointment with your midwife.

Who can take part in the study?

To take part in the study you should be:

- Aged 16 years or over
- Currently pregnant
- Planning a vaginal birth (not planning a caesarean)
- Wishing to receive an intrauterine device (hormonal or non-hormonal) for contraception within the first 48 hours after birth

- Suitable to have an IUD for contraception (It may not be possible for some individuals, for example those with an unusually shaped womb due to large fibroids)
- Able to understand written and spoken English
- Able to consent to take part

What will happen if I take part?

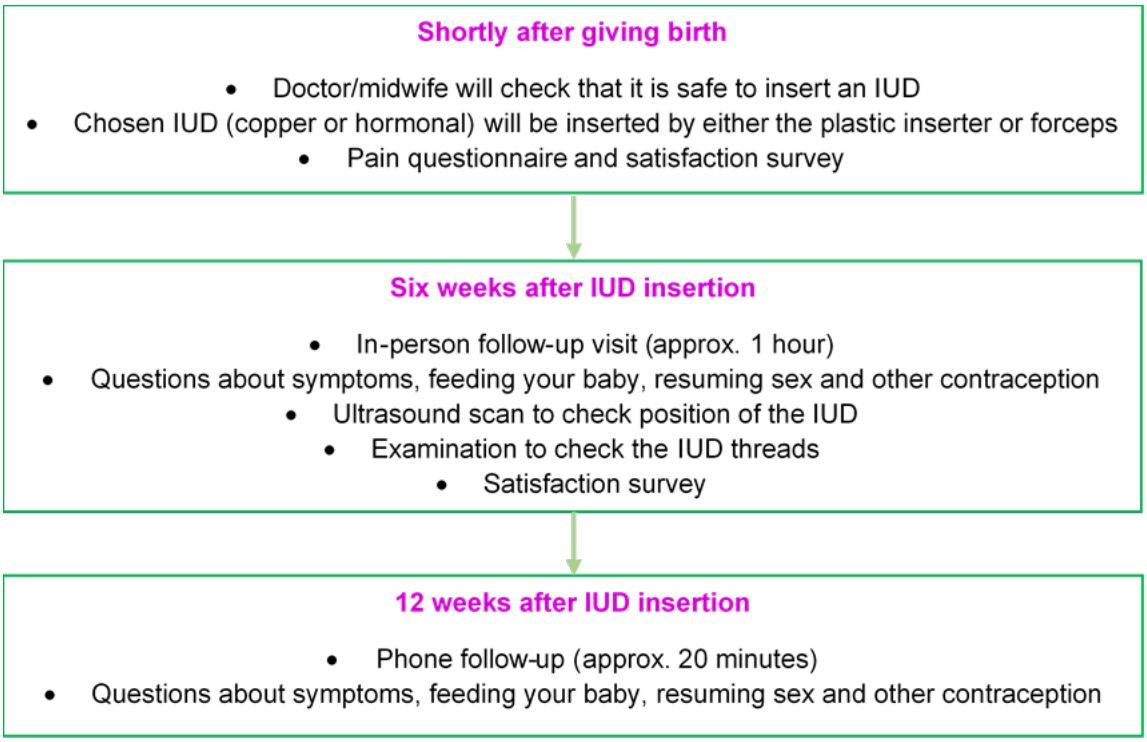


Image showing an overview of what happens if you take part. Please read the text below for details.

During Pregnancy:

If you agree to take part in the study, you will receive the usual care during your pregnancy. There will be no extra scans or tests performed. We will include a note on your maternity record to indicate that you are taking part in the study and what your chosen type of IUD is (hormonal or copper). Once you have signed the consent form and a member of the research team has confirmed you are able to take part in the study you will be allocated at random to one of the two insertion methods – either the standard metal tongs or the new plastic inserter. By agreeing to take part in the study, you agree to receive your chosen type of IUD by either of the insertion methods. You will not be able to choose the insertion method or know which group you have been allocated to. Only the research team and the doctor or midwife inserting the IUD will know which one of the two study groups you have been allocated.

When you attend the hospital or birth centre to have your baby, the team will be notified that you are planning to have an IUD inserted.

At Birth:

Shortly after your baby is born, one of the midwives or doctors will attend to insert the IUD for you. This will happen in the same place that you had your baby, for example in a room on the labour ward, birth centre or in theatre (if you require an assisted birth). This will usually happen within the first few hours of your baby being born, but it can be done anytime up to 48 hours afterwards.

The doctor or midwife inserting the IUD will complete a checklist to make sure it is still OK to go ahead. Sometimes things can happen during your labour or birth that might mean it is not possible to insert the IUD. This would include if you experienced a lot of bleeding at the time of birth, if you are being treated for a possible infection or if there is a gap of more than 36 hours between your waters breaking and your baby being born (because of the higher chance of infection).

If it is safe to go ahead with the IUD insertion, the doctor or midwife will carry out the insertion using the allocated method.

If you are allocated to the standard metal tongs technique and:

- You have chosen a copper IUD, the pre-packaged IUD in the PPIUD inserter will be removed from the plastic insertion tube and inserted using forceps.
- you have chosen a hormonal IUD, the IUD will be removed from its standard plastic insertion tube and inserted using forceps.

If you are allocated to the new plastic inserter technique and:

- You have chosen a copper IUD, the new postpartum inserter comes with the IUD already in it and we will use this for insertion as it is.
- you have chosen a hormonal IUD, we will remove the copper IUD from the inserter and place a hormonal IUD into the PPIUD plastic tube instead.

During the IUD insertion you will be asked to be in a position called "lithotomy", which is when you lie on your back with your legs raised and supported. Sterile sheets or covers are then used to keep the area clean and to cover your legs. This setup ensures that you cannot see the device being used to insert the IUD, so you are not influenced in any way.

You 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). You will also be asked to complete a short satisfaction survey.

After the IUD procedure, you will receive normal postnatal care. You will not have to stay in hospital any longer than usual and you can choose to feed your baby anyway you like.

[If it is not safe to go ahead with the IUD insertion at this time or we are unable to insert the IUD for other reasons, you will be offered the option of having this done at the routine clinical check-up visit a few weeks later as part of your usual postnatal care. You may be offered alternative contraception to use in the meantime. We will follow-up with you by telephone approximately 6 and 12 weeks after the IUD insertion to find out if you use any other contraception.]

6 weeks after IUD insertion:

In the first two weeks after your baby is born, you will be contacted by the research midwife to arrange a suitable time to attend a follow-up visit at the clinic. This visit will take place between four and eight weeks after your baby was born. You will attend Chalmers Centre (Edinburgh) for this check-up and travel expenses can be paid. This appointment can take up to 1 hour. You can bring your baby with you to the appointment if you wish.

You will see the research midwife and/or doctor who will ask you some questions about symptoms you have noticed since the IUD was inserted, including if the IUD has fallen out. You will also be asked questions about how you are feeding your baby (breastmilk or formula), if or when you resumed sex after your baby was born and any other contraception used (such as condoms). You will also be asked to complete a short satisfaction survey about your experience of the IUD.

You will then receive an ultrasound scan to check the position of the IUD inside the womb. This will be a transvaginal scan – which involves passing a thin probe gently inside the vagina for around 5 minutes. It is not usually painful. After this, we will perform a gentle examination using a speculum (a plastic device that is placed in the vagina and opened to be able to view the cervix) and to check for the IUD threads and trim them if necessary.

If the IUD is not in the correct position, we will remove it during the examination. If the IUD is removed, or has fallen out, you can choose to have another IUD inserted during this visit (or a later date). Alternatively, you can choose to start a different method of contraception which we can provide for you. If the IUD is not seen on the ultrasound, and it is not known to have fallen out, we will arrange for you to have a pelvic x-ray. This is normal process to exclude the very rare risk of a uterine perforation during the IUD insertion procedure.

12 weeks after IUD insertion:

The research team will contact you again by email or phone (whichever you prefer) around 6 weeks later (12 weeks after your baby was born and you had the IUD inserted) to organise a telephone follow-up. You will be asked questions about any symptoms you have noticed, how you are feeding your baby (breastmilk or formula), if or when you resumed sex after your baby was born and any other contraception used (such as condoms). It will take around 20 minutes to answer the questions. We will arrange the call for a time that is convenient for you. This is the last activity you will be involved in during the research study.

Is there anything I need to do or avoid?

You will be asked to avoid having unprotected sex until you attend the follow-up appointment six weeks after your baby was born and you had the IUD is inserted to check it is in the correct position. This is the usual advice when an IUD is inserted at birth and is to reduce the small chance of an unexpected pregnancy arising from an IUD that might have fallen out without the individual being aware of this. If you do wish to have sex before then, you can use alternative contraception such as condoms.

What are the possible benefits of taking part?

In routine NHS care, any individual who receives an IUD at the time of birth is advised to make and attend an appointment at their GP practice around six weeks later for a check of their IUD threads. If the threads of the IUD are not seen at this appointment, they are referred by their GP to have an ultrasound scan at the hospital. With current NHS waiting times they might have to wait a few weeks to have this done.

By taking part in this study, we will arrange the follow-up IUD threads check-up with the research team at a time that is convenient for you. This appointment will take place in a specialist clinic and replace the standard check-up at your GP practice mentioned above. We will be able to perform all the usual checks for you, including an ultrasound scan, at the same visit. This might mean fewer appointments for you and a shorter waiting time.

Otherwise, there are no direct benefits to you taking part in this study, but the results might help to improve the healthcare of patients in the future. The results of this study may be used for the future commercial development of a new medical product. Your participation in this study will not entitle you to benefit financially from the commercial development of the product.

What are the possible disadvantages of taking part?

IUD insertion is a common and safe procedure. IUDs are one of the most effective forms of contraception, with fewer than 1 in 100 people who use an IUD getting pregnant in one year. However, in the unlikely event that pregnancy occurs while using an IUD, there may be risk of spontaneous abortion, sepsis or ectopic pregnancy (pregnancy outside of the womb). Certain medication e.g. antiplatelets may make you more prone to risks, the research team will discuss this with you.

There are some known risks of IUD insertion which will be discussed with you. These risks are similar whether you have the IUD inserted at the time of birth or not and whether you have your IUD inserted as part of this study 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. The chance of these risks happening might be slightly different when you have an IUD fitted shortly after birth. For example, current evidence suggests that infection rates are similar, uterine perforation rates are lower (due to the thicker uterine wall after delivery), there may be a higher chance of the IUD being expelled (falling out) as the womb returns back to its usual size after birth and pain may be similar or reduced. This evidence is drawn largely from insertion procedures performed manually or using metal forceps.

When the new plastic inserter was tested previously in other countries, no significant additional risks have been identified whether you have the IUD fitted with the plastic inserter or metal tongs. However please note that previous studies did not test the new plastic inserter with a hormonal IUD. There is a risk that a hormonal IUD may not be as stable within in the inserter tube or may not release as smoothly from the inserter as the copper IUD. We do not know what, if any, disadvantages this could cause for you, but we will evaluate this as part of the study.

If you choose to have an IUD inserted as part of the study there are some extra steps and time that will be required. These include:

- Screening/consent appointment (up to 30 minutes)
- Brief questionnaire about pain at the time the IUD is inserted (5 minutes)
- Follow-up visit at the research clinic instead of at your GP practice (Chalmers Centre in Edinburgh) – up to 1 hour (travel expenses will be paid)
- Telephone questionnaire – up to 20 minutes

What if there are any problems?

If you have a concern about any aspect of this study, please contact Karen McCabe (research midwife) on 07973 760871 who will do their best to answer your questions.

In the unlikely event that something goes wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for

compensation against NHS Lothian but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

What will happen if I don't want to carry on with the study?

You are free to withdraw from the study at any time. The reasons you give for this will be recorded, but you do not need to give a reason if you do not wish to do so. Data collected up until that point may still be used to inform the study unless you specifically ask it not to be.

If you leave the study **before** the IUD is fitted, we will not invite you to attend any research visits, however we will ask if we can follow up with you by telephone approximately 6 weeks and 12 weeks after you gave birth to find out if you use any other contraception. You can still choose to have an IUD fitted after birth through the usual NHS pathways. You can also choose a different method of contraception if you prefer, which will be provided for you by maternity staff.

If you leave the study **after** the IUD is fitted, we will still offer you a check-up appointment approximately 6 weeks after you gave birth. This is to check the position of the IUD and for any safety issues. You can choose whether the information from this check-up visit is included in the study or not.
If you decide **not** to attend the 6-week check-up with the research team, it is important that you attend your GP practice to have the IUD checked.

What happens when the study is finished?

You will return to usual NHS care after the study ends. The IUD can remain in place and continue to be used for contraception up until its expiry date (8 years for hormonal IUD, 10 years for copper IUD). You can have it removed at any time you wish through your usual contraceptive provider. This might be at your GP practice or local sexual health clinic.

Your data will be stored securely and in alignment with the General Data Protection Regulations and confidentiality agreements. Your data will be viewed by approved colleagues only from the local study team, University of Edinburgh Clinical Trials Unit and individuals from the trial sponsor and regulatory authority.

We will seek permission from you for your local study team to hold personal data for up to 12 months after the end of the research but this will be deleted as soon as they are no longer required. This is in case we wish to contact you in future to invite you to take part in future ethically approved studies. This is optional. If you do not wish to consent to this, your participation in this study is not affected.

The research team might make the study data available for other researchers (in the UK and abroad) and the manufacturer to look at. Before we make it available, we will make sure it

does not contain any of your personal data so that you will not be identifiable. In future, non-identifiable data from this study could be used to provide evidence to support a license application to regulatory authorities for the IUD inserter (or similar) to be used in clinical settings.

In the event that you become pregnant while in the study, we will check your medical records until 1-2 months after the due date of the baby to review the outcome of the pregnancy. This is a normal precaution that is generally applied to all research studies.

Will my taking part be kept confidential?

As routine, we will inform your GP that you are taking part in this study. All the information we collect during the course of the research will be kept confidential and there are strict laws which safeguard your privacy at every stage.

How will we use information about you?

We will need to use information from you and your medical records for this research project.

We will collect your Community Health Index (CHI) number or NHS number. Note that the CHI is a population register, used in Scotland for health care purposes. The CHI number uniquely identifies a person on the index and is personal identifiable information. Your CHI number is being collected to allow us to retrieve specific information from labour and delivery record, and to record any complications that occur while you are part of the study.

Other personal identifiable information collected will include your:

- Name
- Date of birth
- Ethnicity
- Height, weight and BMI at booking appointment
- Contact details - post code/ telephone number / e-mail address
- GP details – to let them know you are taking part in the study

People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number assigned instead.

The University of Edinburgh and Lothian Health Board are the Sponsor of this research, and is responsible for looking after your information. We will keep all information about you safe and secure by:

- We will keep all identifiable information about you safe and secure within the research team office at NHS Lothian (Chalmers Sexual Health Centre) and will only hold this to contact you regarding the study.

- Once the study is complete this will be destroyed unless you consent to be contacted about other studies in which case your contact details will be kept for a maximum of 12 months within the research team office at NHS Lothian (Chalmers Sexual Health Centre).
- Non identifiable information and data we generate from the study will be held on a bespoke web-based database provided and maintained by the University of Edinburgh Clinical Trials Unit. Once we have finished the study, we will check the results and write our reports in a way that no-one can work out that you took part in the study. This data will then be kept for a minimum of 5 years.

International Transfers

We may share data about you outside the UK for research related purposes to:

- Data regarding any safety issues will be sent to the device manufacturer in India. This will not include any personal data.

If this happens, we will only share the data that is needed. We will also make sure you cannot be identified from the data that is shared where possible. This may not be possible under certain circumstances – for instance, if you have a rare illness, it may still be possible to identify you. If your data is shared outside the UK, it will be with the following types of organisations:

- Manufacturer of the PPIUD device.
- Other researchers (in the UK and abroad) to be used for future ethically approved studies.

We will make sure your data is protected. Anyone who accesses your data outside the UK must follow our instructions so that your data has a similar level of protection as it does under UK law. We will make sure your data is safe outside the UK by doing the following:

- Some of the countries your data will be shared with have an adequacy decision in place. This means that we know their laws offer a similar level of protection to data protection laws in the UK.
- We use specific contracts approved for use in the UK which give personal data the same level of protection it has in the UK. For further details visit the Information Commissioner's Office (ICO) website.
- We do not allow those who access your data outside the UK to use it for anything other than what our written contract with them says.
- We need other organisations to have appropriate security measures to protect your data which are consistent with the data security and confidentiality obligations we have. This includes having appropriate measures to protect your data against accidental loss and unauthorised access, use, changes or sharing.
- We have procedures in place to deal with any suspected personal data breach. We will tell you and applicable regulators when there has been a breach of your personal

data when we legally have to. For further details about UK breach reporting rules visit the ICO website.

We will keep your study data for a maximum of 5 years. The study data will then be fully anonymised and securely archived or destroyed.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we have already collected.

If you choose to stop taking part in the study before the IUD is fitted, we would like to follow-up with you by telephone to find out if you are using other contraception. We will only do this with your consent. If you choose to leave the study after the IUD is fitted, we will still offer you a check-up appointment approximately 6 weeks after you gave birth. If you attend this check-up visit, you can choose whether the information from this visit is included in the study or not.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

If you agree to take part in this study, you will also have the option to allow the research team (within NHS Lothian) to securely store your contact details and agree to be contacted about other ethically approved research studies. You will only be contacted by a member of this research team to determine if you are interested in taking part in another research study. Your verbal consent may then be sought to pass your contact details to another research team within the University of Edinburgh and/or NHS Lothian. Agreeing to be contacted does not mean you are obliged you to take part in any further studies.

You have the right to ask us to remove, change or delete data we hold about you for the purposes of the study. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.

Where can you find out more about how your information is used?

You can find out more about how we use your information, including the specific mechanism used by us when transferring your personal data out of the UK.

- our leaflet available from www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- by contacting the Data Protection Officer at either:

  - University of Edinburgh: dpa@ed.ac.uk or call 0131 651 4114

- NHS Lothian: Lothian.DPO@nhs.scot or call 0131 465 5444

What will happen to the results of the study?

This study will be written up as publication for a medical journal and the team will aim to present the findings at scientific conferences. A copy will also be available on the Lothian Sexual Health website (https://www.lothiansexualhealth.scot/research). You will not be identifiable from any published results.

If you wish to see a copy of the results of the study you can email chalmersresearch@ed.ac.uk. These will not be available until after the study has been completed.
The results will also be publicly accessible on the research registry ISRCTN. ISRCTN - Search results ISRCTN71047458.

Who is organising and funding the research?

This study has been organised by University of Edinburgh and NHS Lothian. It is jointly funded by the Chief Scientist Office in Scotland, and a local charity known as the Edinburgh Family Planning Trust.

Who has reviewed the study?

The study proposal has been reviewed by a team of patient representatives who have had personal experience of IUD insertion at the time of birth.

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee. A favourable ethical opinion has been obtained from North West - Greater Manchester South Research Ethics Committee 25/NW/0226.The study has also been approved by the Medicines & Healthcare products Regulatory Agency (MHRA). NHS Management Approval has also been given.

Researcher Contact Details

If you have any further questions about the study, please contact the local research team: Karen McCabe (research midwife) on 07973 760871 or email: chalmers.research@ed.ac.uk

Independent Contact Details

If you would like to discuss this study with someone independent of the study, please contact Dr Katie Boog (NHS Lothian) at: katie.boog2@nhs.scot.

Complaints

If you wish to make a complaint about the study please contact:

Patient Experience Team – NHS Lothian
Mainpoint
102 Westport
Edinburgh
EH3 9DN

By telephone
0131 536 3370 (open Mon-Fri, 9am to 2pm)

By email
LOTH.Feedback@nhs.scot

Participant ID: **Centre ID (if applicable)**

CONSENT FORM

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

Please **initial** box

1. I confirm that I have read and understand the information sheet for the above study.

*Date (DD MMM YYYY)	*Version Number

**complete during consent process*

2. I have had the opportunity to consider the information, ask questions and have had these questions answered satisfactorily. ☐
3. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and without my medical care and/or legal rights being affected. ☐
4. I give permission for the research team to access my medical records for the purposes of this research study. ☐
5. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the Sponsor (University of Edinburgh and/or NHS Lothian), from regulatory authorities or from the NHS organisation where it is relevant to my taking part in this research. I give permission for these individuals to have access to my data and/or medical records. ☐
6. I give permission for my personal information (including name, CHI number, date of birth, ethnicity, postcode, telephone number, email address, and consent form) to be collected and stored in NHS Lothian for administration of the study. ☐
7. I give permission for some of my indirectly identifiable data (age in years, ethnicity and Scottish Index of Multiple Deprivation) to be entered onto the secure trial database, which is managed by the University of Edinburgh. ☐
8. I agree to my General Practitioner being informed of my participation in the study. ☐
9. I understand that data collected about me during the study may be converted to anonymised data and shared with other researchers (in the UK and abroad) to be used for future ethically approved studies. ☐
10. I agree to be randomised to receive IUD insertion by either of the techniques described. ☐
11. I understand that it may not be possible to go ahead with the IUD insertion after I gave birth as planned. If this is the case, I agree to be contacted by telephone approximately 6 and 12 weeks after the birth to find out if I am using other contraception. ☐

Please **initial** box

12. I agree to be contacted about ethically approved research studies for which I may be suitable. I understand that agreeing to be contacted does not oblige me to participate in any further studies. Yes ☐ No ☐
13. I understand that the data generated during this study may be used for future commercial development of products and I will not benefit financially from this. ☐
14. I understand that data generated during the study will be sent outside of the UK / European Economic Area where laws protecting my personal information may be different to my own country. In particular, I understand that data regarding safety generated during the study will be sent to the device manufacturer in India. ☐
15. I agree to take part in the above study. ☐

Name of Person Giving Consent	Date	Signature
Name of Person Receiving Consent	Date	Signature

Designation of Person Receiving Consent (e.g. Principal Investigator)

1x original – into Site File; 1x copy – to Participant; 1x copy – into medical record