PARTICIPANT INFORMATION AND CONSENT FORM



 **Short study title: MOLI**

**Full study title: Mifepristone Outpatient Labour Induction**

**Chief Investigator: Prof. Mark R Johnson**

**Sponsor reference: CW003**

**IRAS number: 1004485**

**Version: 8.0**

**Principal Investigator: Alexander Steshenko**

**Introduction:**

**This leaflet provides information about a new labour induction study**

It includes details that can help you decide if you want to join.

• Part one explains why the study is being run and what your participation would involve.

• Part two includes more detailed information.

You can take the leaflet home to discuss it with your friends and family. Please take your time to decide whether you wish to take part.

Your doctor and the research team are happy to answer any questions.

**Part 1- Information about this study**

1. What is the purpose of the study?

Labour is induced in 1 in 3 pregnancies in the UK. Some women and birthing people have fed back that current methods of labour induction can be slow, uncomfortable and are not always successful. This study is looking at whether a medicine called Mifepristone might be more successful and quicker than our usual methods.

Mifepristone is already widely and safely used by pregnant women for other reasons, but currently, it is not used to induce labour as we are not sure how effective it is.

Current information suggests that mifepristone increases your chance of going into labour before the hospital induction date, improves your chance of having a vaginal delivery, shortens your hospital stay, and is safe for your baby. This study aims to see if this is true.

1. Why have I been invited to join?
* You have been invited because you are currently pregnant
* You are a healthy individual
* Your pregnancy has been going well
* You are currently considering induction of labour from **36 weeks + 5 days to 41 weeks + 5 days**
* You have not had a previous Caesarean section.
1. How many people are in the study?

The study will enroll 400 pregnant women.

1. Do I have to take part?

It is up to you to decide to join the study. We will explain the study and go through this information sheet with you. If you choose not to take part in the study, your care will not be affected, and you will go through the standard pathway for induction of labour as discussed with the midwife booking the induction.

If you agree to take part, we will ask you to sign a consent form. You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive*.* If you withdraw from the study we will destroy all your collected samples but we will ask to use the data we have collected up to the time of your withdrawal.

1. What will happen to me if I take part?

The study doctor and the research team will collect your medical information, including medical history and current medicines from your notes as part of the study.

The two treatment groups in this study are:

* Mifepristone + standard care
* Placebo + standard care

The placebo is identical to the mifepristone tablet, but without any mifepristone in it. Whether you receive mifepristone or placebo is decided randomly, like flipping a coin. You will have a 50% chance of receiving either mifepristone or placebo.

This trial is a double-blind trial which means neither you nor the study staff will know which treatment you are receiving. If needed the study staff are able to find out what treatment you were allocated to.

If you agree to take part in the study, your treatment will be the same as if you were undergoing a normal induction except that two days before your induction, we will need to do a vaginal examination to make sure you are eligible for the study (to check your cervix).

The timings of the study are set out below:

**Initial contact**

Study personnel will discuss the study with you and confirm your eligibility to take part.

**Visit 1: 2 Days Before Your Induction of Labour**

If you are interested in taking part, the study team will see you 2 days before your induction is planned discuss the study with you again. If you agree to take part in the study, we will monitor your temperature, blood pressure, heart rate and breathing rate. We will assess the wellbeing of your baby by monitoring your baby’s heart rate and womb activity using a CTG machine. Next, if you have not had a vaginal examination within 2 days, we will assess the neck of your womb (the cervix) to confirm that it is closed and that you are suitable for the study. If your cervix is open already, you will not be suitable to take part in the study and you will continue with your regular clinical care.

If you are suitable, we will then give you the treatment. We request that you do not consume any grapefruit juice until after birth, as this can affect your body’s response to the treatment. The visit will take about one hour. We will arrange to see you again 2 days later if you have not gone into labour.

**Visit 2: Your Induction of Labour**

If you have not gone into labour by 2 days after visit 1, then you will return to hospital for visit 2 to start your induction of labour as part of your normal clinical care. If you have gone into labour, you will not need to participate in visit 2 and you will move directly to visit 3.

At this visit, we will monitor your temperature, blood pressure, heart rate and breathing rate. We will assess the wellbeing of your baby by monitoring your baby’s heart rate and womb activity using a CTG machine. We will ask how you are feeling and if you have noticed any changes since taking the medication. We will then perform a vaginal examination and discuss the next steps with you.

* If your cervix is still closed, we will suggest using a Propess pessary. This releases prostaglandins which helps the cervix to open and stimulates the womb to contract. It has a string attached to it which means that it can be removed if you start to contract too often which can happen after the mifepristone treatment.
* If your cervix is slightly open, we may discuss using either a balloon or other ways to help your cervix open further.
* If your cervix is open enough, we will transfer you to the labour ward to have your waters broken. This may be sufficient to make you labour alone, but sometimes we need to use an oxytocin hormone drip to make the womb contract. Because the mifepristone may make you more sensitive to oxytocin, we will start the drip at a lower rate. This may delay your induction by 30 minutes but will avoid you over-responding to the drip.

The assessment will take 30-40 minutes and you may stay in the hospital until you birth your baby, depending on the induction method you and your clinician choose.

You may go into labour at any time after taking the medication. If you feel contractions happening more than 2 times in 10 minutes, we will ask you to come to the Maternity Assessment Suite (MAS). Here you will be assessed by the MAS staff and cared for as usual. If your labour slows down and you may need an oxytocin drip, it will be started at a lower dose as we discussed above. Otherwise, your care will be the same as usual including having pain relief when you need it.

**Visit 3: After the birth of your baby**

After birth, we will carefully monitor your baby particularly making sure your baby’s sugar level is normal. It is theoretically possible that a baby’s blood sugar may be lower after the mother is given mifepristone, but none of the previous studies have found this to be the case. Your baby will have at least two extra heel-prick blood tests 3-8 hours after birth, to monitor for low blood sugar.

After birth, while you are still in the hospital, we will talk to you about your experience of induction and labour. We will record information about your baby, such as birth weight, the Apgar score, paired cord gases, whether your baby is admitted to the special care baby unit and reasons for admission and about you, including your temperature, blood pressure, heart rate, and breathing rate which are routinely monitored after birth.

We will ask you to complete a short questionnaire about the study. This will take no more than 30 minutes.

**Visit 4: Follow up 6 weeks after birth**

Six weeks after the birth of your baby, we will arrange a phone call when it is convenient. We will ask you questions regarding any side-effects you or your baby may have encountered and document them on our record document sheet. We will ask you to complete a short questionnaire about how you are and your experience. The phone call will take no more than 20 minutes.

1. How long is the study?

The study lasts until you give birth, but we will call you around 6 weeks after birth to check on you and your baby.

1. What are the possible benefits of taking part?

The possible benefit of taking part in this study is that it may help start labour before the induction, make your induction more likely to succeed, and reduce the time you spend in hospital. It may also benefit other women, just like you, in the future.

1. What are the possible risks of taking part?

All medicines have the potential to cause side effects. The main side effects observed with Mifepristone when used in the induction of labour are:

|  |  |
| --- | --- |
| **Risks** | **Side effects** |
| **Common**: can affect between 1 in 10 to 1 in 100 people | * Nausea
* Vomiting
* Diarrhoea
 |
| **Uncommon**: can affect between 1 in 100 to 1 in 1000 people | * Low blood pressure
* Skin rashes
 |
| **Rare**: can affect less than 1 in 1000 people | * Headache
* Hot flushes
* Dizziness
* Hives
* Skin inflammation
* General feeling of discomfort, illness of lack of well-being
 |
| **Very rare**: can effect less than 1 in 10,000 people | * Swelling underneath the skin
 |

However, not all side effects are known so please tell the study doctor if you feel different in anyway after the administration of the treatment.

Mifepristone makes the womb more sensitive to the drugs used for inducing labour. This reduces the need for a Caesarean section but means you may over respond to the drugs we sometimes use to induce labour (prostaglandins or oxytocin). To reduce this possibility, we will use a prostaglandin pessary, which can be removed if needed, and start oxytocin at a lower dose.

1. What is mifepristone used for currently?

Mifepristone works by blocking progesterone, which may make labour start. In some countries, mifepristone is used routinely to induce labour in normal pregnancies. In trials to date, over 2,000 women with uncomplicated pregnancies have used mifepristone to induce their labour. These studies have shown that mifepristone is effective and safe, but the small numbers mean that we need more evidence before it can be introduced routinely in the NHS. Currently in the NHS, mifepristone is used to start labour in women who have had a miscarriage, a medical termination of pregnancy, or after late pregnancy complications.

1. What if there is a problem?

If you are unhappy with the study, please let the research team know.

Contact: King’s Research Team : kch-tr.kingsresearchmidwives@nhs.net or **(**:07974045041 - King's College Hospital Team
**(**:07974045056 - Princess Royal University Hospital Team

This includes if you are unhappy with the way you have been treated. It can also include if you feel you have come to harm.

You can also make a formal complaint to NHS PALS without involving the study team.

Contact PALS (Patient Advisory and Liaison Service) at: Call 020 3299 4618 · Email. kings.pals@nhs.net

1. Will taking part in this study be kept confidential?

In this research study we will use information from you, your baby, your medical records and your GP. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study.

Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules. At the end of the study, we will save some of the data in case we need to check it and for future research. We will make sure no-one can work out who you and your baby are from the reports we write.

See Part 2 for details of who will see your information.

1. Who is organising and funding the research?

This study is sponsored by Chelsea and Westminster Hospital NHS Foundation Trust. It is funded by Nordic Pharma, who developed and market mifepristone.

**Further information and contact details**

If you would like more information, please call the King’s Maternity research team on 07974 045056

**This is the end of Part 1 of the information sheet.**

If you are interested in the study, please read the information in Part 2 before deciding if you want to join.

**Part 2 - Other detailed information**

1. What if relevant new information becomes available?

If new information about mifepristone becomes available, your research doctor will tell you about it. If the study is stopped for any other reason, you will also be told why. In both cases your regular induction of labour care will continue outside the study.

1. Can I leave the study?

Yes, you can leave the study at any time. You can also do this without giving a reason. However, talking to one of the study team about the reasons can help researchers design better studies in the future.

To leave the study, simply tell your care team that you no longer want to take part. If you do leave the study, the information until this point will still be used. Any stored blood or tissue samples that can still be identified as yours will be destroyed if you wish. Please let the study team know if you want them to be destroyed.

1. What if something goes wrong?

In the event that something does go 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 Chelsea and Westminster NHS Foundation Trust, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

1. How will we use information about you?

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

This information will include your initials, local patient number, name, contact details and date of birth of you and your baby. We will use this information to do the research, or to check your records to make sure that the research has been done properly.

People who do not need to know who you and your baby are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Some of your information will be sent to within or outside of the European Economic Area. They must follow our rules about keeping your information safe. We may share data about you outside the UK for research related purposes to:

* Data may be shared with a clinical research data collection software service based in the EU, to collect and analyse the data from the research trial. Your data will be assigned a code number, so people will not be able to see your name or identify who you are. Only the staff involved in your direct clinical care can identify who you are from the code number.
* Data may be shared with the organisation who develop and market mifepristone, to monitor the safety of mifepristone and progress of the research trial. Your data will be assigned a code number, so people will not be able to see your name or identify who you are. Only the staff involved in your direct clinical care can identify who you are from the code number.

If this happens, we will only share the data that is needed. We will also make sure you can’t be identified from the data that is shared. If your data is shared outside the UK, it will be with the following sorts of organisations:

* our partners who assist in the collection, analysis and storage of your data
* our partners who develop and market mifepristone

We will make sure your data is protected. Anyone who accesses your data outside the UK must do what we tell them 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:

* 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 Information Commissioner's Office (ICO) website

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you and your baby took part in the study.

1. 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 already have.

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.

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 and your baby.

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

You can find out more about how we use your information

* at [www.hra.nhs.uk/patientdataandresearch](http://www.hra.nhs.uk/patientdataandresearch)
* by asking one of the research team
* by sending an email to  kch-tr.kingsresearchmidwives@nhs.net or by emailing the Data Protection Office (DPO) at the Trust on : kch-tr.dpo@nhs.net
* by ringing us on:**(**:07974 045041 - King's College Hospital Team
 **(**:07974 045056 - Princess Royal University Hospital Team

Your personal data and research data will be securely archived for 25 years after the study has ended as per regulatory requirements.

1. What will happen with the results of the study?

As with all research, the results will be published. This will be at medical meetings and in research journals. The results will also be reported to the organisations that approve medicines.

You and your baby will not be identified in any of these reports. For further information on the results of the study, speak with your study doctor.

1. Who has reviewed the study?

All research in the NHS needs to be approved by independent experts. This group is called a Research Ethics Committee. This review is to protect your rights, safety dignity and well-being.

The board includes medical staff as well as members of the public whose expertise is outside medicine. This study was reviewed and approved by London - Fulham Research Ethics Committee.

1. Contact for further information

If you have any questions at this point please ask the person consenting you for the study. In case of further questions, please contact:

King’s College NHS Foundation Trust Research Team

Princess Royal University Hospital

Farnborough Common

Orpington Kent

BR6 8ND

Tel: **(**:07974 045041 - King's College Hospital Team
 **(**:07974 045056 - Princess Royal University Hospital Team

**This completes Part 2 of the information sheet.**

**Consent Form**

**Chief Investigator:** **Prof. Mark Johnson IRAS Number**: **1004485**

**Version: 8.0 Date: 04 December 2024**

**Principal Investigator: Patient ID number:**

 **Please initial box**

1. I confirm that I have read and understand the information sheet (version 8.0 dated 04 December 2024) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.
3. I understand that relevant sections of any of my medical notes and data collected during the study may be looked at by responsible individuals from Chelsea and Westminster Hospital NHS Foundation Trust, or from regulatory authorities, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.
4. I agree that my pseudonymised data generated during this study may be sent within or outside of the UK.
5. I agree to my GP being informed of my participation in this study and for my GP to disclose information about my medical status to the study doctor.
6. I give consent for the information of my baby to be collected and analysed for the trial.
7. I agree to take part in the above study.
8. I understand that I will be given a signed copy of this document to keep.

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Name of participant [PRINT] Date Signature

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Name of person taking Date Signature

Consent [PRINT]

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Name of witness Date Signature

(if applicable)

When completed: 1 copy for participant; 1 (original) for researcher site file; 1 copy in medical notes.