Thank you for taking the time to read this information.

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This study is being funded by Medicem and independently conducted by the University of Birmingham and Birmingham Women's and Children's Hospital.

The Clinical Trials Unit (BCTU) is dedicated to improving the care provided to women and their families during pregnancy and childbirth (www.Birmingham.ac.uk/BCTU)

Local Header to be placed here

SOLVE
Participant Information Leaflet

A randomised controlled trial of a Synthetic Osmotic cervical dilator for induction of Labour in comparison to dinoprostone Vaginal insErt

LOCAL HOSPITAL SOLVE RESEARCH STAFF CONTACT DETAILS:

LEAD SOLVE STUDY DOCTOR NAME:

LEAD SOLVE STUDY DOCTOR TEL:

SOLVE STUDY RESEARCH MIDWIFE NAME:

SOLVE STUDY RESEARCH MIDWIFE TEL:

Patient Advice & Information Liaison Service (or equivalent):

ISRCTN: 20131893 REC:17/EM/0011 EudraCT:2016-004726-42 IRAS:208770

Participant Information Leaflet: This tells you the purpose of the study and what will happen to you if you take part.

Invitation to join the SOLVE study

You are invited to take part in a research study called the SOLVE study. The study is for pregnant women who require help to induce their labour. It will find out which method of induction is more effective in bringing on labour.

Before you decide, 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. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether you would consider taking part. If you decide not to take part, this will not affect the standard of care you will receive.

The rest of this leaflet explains the study in more detail and describes what being in the study would mean for you.

What is the purpose of the study?

Some women expecting babies may need help going in to labour, or need to bring the birth of their child forward, for a number of reasons. The first step is to make the cervix (neck of the womb) open up, shorten and soften, which is called ripening. There are different methods that can be used to help ripening. These include a pessary called dinoprostone (or PROPESS) that is placed in the vagina. This provides a hormone that helps to prepare the cervix for labour. In the UK this drug is usually given to women expecting their first baby and is sometimes given to women in subsequent pregnancies. It is effective but can have side effects.

In recent years there has been more interest in using non-drug methods of ripening, as these have fewer side effects, but may not be as fast at bringing on labour as drugs. The study would like to find out if a new method, using a cervical dilator (called DILAPAN-S) to stimulate the cervix in to labour, would be more effective. The SOLVE study will find this out.

Why am I being asked to consider the study?

You are being asked to consider taking part in this study because the midwives and doctors caring for you are expecting you to have an induction of labour. The study will invite **860** women to take part, half of whom will receive PROPESS and half will receive DILAPAN-S.

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 asked to sign a consent form and you should keep this leaflet. You are still free to withdraw at any time and without giving a reason. Women outside the study will not be offered DILAPAN-S for induction of labour. Whether or not you are in the study, the standard of care you receive will not be affected.

What would happen to me if I take part?

If you are happy to take part in the study, you will be asked to sign a consent form. The person who takes consent will then enter your details into a telephone system. This will allocate you to either the PROPESS or the DILAPAN-S group. The decision about which group you would go into will be made by chance, rather like the toss of a coin. This is important because it ensures that the two methods of induction can be tested fairly against each other. We will also let your GP know that you took part in the SOLVE study, with your consent.

1) PROPESS – a dinoprostone vaginal pessary

PROPESS (which looks like a flat tampon with a string attached) is inserted close to the opening to the cervix. The hormone dinoprostone is then released slowly to make the cervix ripen. Women will need to remain in hospital once PROPESS has been given.

2) DILAPAN-S – a synthetic osmotic cervical dilator

DILAPAN-S are thin rods made of material which absorb fluids. After their insertion into the cervix, they gradually increase their diameter and thus open the cervix. As they dilate the cervix, the rods stimulate the release of your own hormones and the cervix ripens naturally. Three or four rods are usually inserted.

What about repeat doses of PROPESS/replacement DILAPAN-S rods?

If the cervix is ripening slowly, but you and your baby are well, the initial method will be removed and may be replaced. You may be offered a second pessary after 24-32 hours (if in the PROPESS group) or a second set of DILAPAN-S rods after 12 hours (if in the DILAPAN-S group). If the cervix is ripened but contractions have not started, your waters are broken artificially and an oxytocin infusion is started to allow labour to progress (women given Dilapan-S have a 40% chance of receiving oxytocin compared to a 20% chance for women given Propess). Taking part in the study won't affect the care you receive, and you will be cared for as you would ordinarily within the NHS.

What does being in the study involve?

Information about your labour will be collected by the midwife and be kept confidentially. We will record details of your childbirth experience and any infections you and your baby acquire whilst in hospital. You will also be asked to fill in a short questionnaire about your labour experience. There are no further tests or hospital visits connected with this study. No payments are available for taking part in this study.

What are the possible benefits of taking part?

You will be offered an induction if you need one, whether you participate in the study or not. We cannot promise the study will help you as an individual, but the answers we get from this study will help improve the care provided to women requiring induction of labour in the future. There might be other methods available to induce labour at this hospital (e.g. balloon catheter), but these are not being researched in the SOLVE study.

Are there any side effects or risks involved?

Women can experience side effects with PROPESS. The main risk is that contractions become too strong and your baby becomes distressed. This may happen for 1 in 20 women. Women may experience discomfort with the DILAPAN-S, and there may be a small risk of infection (1 in 100 000 women). There is also a rare risk of the pessary or rod(s) becoming trapped in the vagina or cervix, fragmenting on removal, or retracting in to the uterus (5 in 100 000 women). Should this happen your doctor may need to use forceps, or other intervention, to help remove them. You will be monitored by a midwife whilst you are being induced.

Will my taking part in this study be kept confidential?

Yes, all information collected in the study will remain strictly confidential, similar to your medical records. If you take part, the study team will record information on a secure database hosted by the University of Birmingham. Information about your labour and treatment, that is transferred out of the hospital, will be identified by a code only. The consent form will be collected by the organisers to check this is correctly signed.

Can I withdraw from the study?

You are free to withdraw at any time, without giving a reason and without your standard of care being affected. If you do decide to withdraw, once induction has started, it may not be possible to remove the method used for induction or change the method used, as you still need labour to be induced. We would still use the data already collected up to that point, and would still like to know your baby's day and time of birth, unless you explicitly express that this should not happen.

Is it possible to choose DILAPAN-S without taking part in the study?

The hospitals taking part in this research study do not routinely offer DILAPAN-S for induction of labour. Therefore, it will be only available as part of the study.

Who is organising and funding the research?

The University of Birmingham Clinical Trials Unit is organising this research. Birmingham Women's and Children's Hospital NHS Foundation Trust is acting as sponsor. The manufacturer of DILAPAN-S (Medicem) is funding the research and will be collecting any relevant safety information.

Who has approved the study?

This study has been reviewed by NHS Research and Ethics Committee East Midlands Leicester Central (REC). The REC looks after the rights, well-being and dignity of participants.

Can I seek independent advice about participation?

If you would like more information about the study itself you can ask to speak to the lead doctor or midwife for the SOLVE study at this hospital. These contact details are on the front page of this leaflet. The hospital trust's Research and Development (R&D) office can also be contacted. They will give you advice about how to contact someone for independent advice.

What if there is a problem?

If you are worried about any aspect of this study, you should first speak to the lead doctor or midwife for the SOLVE study at your hospital. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the hospital Patient Advice and Information Liaison Service (PALS), or equivalent, whose contact information is on the front page of the leaflet. If there is a problem with the DILAPAN-S, we will need to record some of your details on a form. Information about you on the form will be identified by a code only. The form will be sent to the University of Birmingham and they will send this form to the manufacturer of DILAPAN-S (Medicem). This process is part of monitoring the safety of DILAPAN-S.

Will participation in the study affect my legal rights?

If you are harmed as a result of negligence then you may have grounds for legal action against the NHS (in respect of any harm which has resulted from any clinical procedure or in respect of any harm solely arising out of participation in the study).

Where can I find the results of the study?

The results of the study will be published in a scientific journal and on the study website (www.birmingham.ac.uk/solve) regardless of the findings. You will not be identified in any report or publication.

To format into a booklet put together as follows:

Back cover/front cover

Pp1/6

Pp5/2

Pp 3/4