What is this Project about and why is it important?

This project relates to induction of labour. Labour is a natural process that usually starts on its own. Sometimes labour needs to be started artificially; this is called ‘induced labour’. Induction of labour is common; 1 in every 5 deliveries in the UK are induced.

Most women have a normal pregnancy and a normal birth, but sometimes it can be best to induce labour: to avoid a pregnancy lasting longer than 42 weeks (known as a prolonged pregnancy), if a woman's waters break but labour does not start, or for other medical reasons.

Clinical trials involve research that is intended to add to medical knowledge and improve the way we treat patients. The results of a clinical trial are reported in terms of ‘outcomes’. A commonly used outcome in induction of labour is ‘mode of delivery’ (the way women deliver after having induction of labour – normal vaginal delivery, assisted vaginal delivery or caesarean section), ‘time from induction to delivery’ or ‘pain relief used during labour’ but other outcomes such as ‘patient satisfaction’ and ‘return to normal activities’ are often reported.

Although trials are designed to ensure that enough patients are examined to give them an accurate result, if we can examine more patients, we can be more confident in the result. When there are lots of trials which look at the same condition, researchers try to put all of the results together so that they undertake an analysis with lots of participants and therefore get a much stronger and reliable result. This method is often used when developing clinical guidelines for different diseases. Unfortunately, trials don’t always report the same outcomes and even if they do, they might measure them in different ways or at a different time. When this happens the results cannot be combined properly and guideline recommendations have to be based on less reliable evidence. If rules were developed that ensured that all trials which examine the same condition had to report the same outcomes it would be much easier to combine results and to develop guidelines. This would allow recommendations about patient care to be based on the strongest available evidence.

Our aim is to prioritise outcomes for induction of labour. We will decide which outcomes should be tested based upon the opinions of doctors, midwives, neonatologists (baby doctors), women representatives and carers. These outcomes will be known as ‘core outcomes sets’ or COS.
Why have you been asked to participate?

We are inviting you to take part in this project because you, or your relative or friend, has undergone induction of labour. It is really important that women, their carers and family are involved when we develop core outcome sets because we need to know which outcomes are most important to them.

There will be no direct benefit to you from participating in this project, however, your participation will help to improve future research into induction of labour and improve the care of women. There are no risks involved in participating in this project.

What will happen if you agree to take part?

We will ask you to confirm your contact details and to provide an email address. These details will all be stored securely. The information you provide will be anonymised during analysis to protect your identity.

There are two different parts of the project that you can become involved in. We would like everyone to consider participating in both parts. You will be able to withdraw from the project at any time if you choose to do so.

Survey

We will invite you to take part in a special survey to help us decide on the final list of core outcomes. The survey will ask you to rate the importance of each outcome. The survey will be internet based and will have two rounds which will be sent out over a 2-month period. It is really important that all two rounds are completed, so that we can reliably use the data. This type of survey is called a Delphi survey.

Prior to the survey, we will send you the list of outcomes and a brief explanation of medical terms. Some questions may be of a sensitive nature. If you have any issues with any questions, we can provide support.

What will happen as a result of the project?

Once the core outcomes sets are finalised they will be publicised so that they can be brought into widespread use. We will do this by presenting them at international conferences, publishing them in specialist journals and registering them on a database that can be accessed by researchers. This will encourage researchers to use core outcomes when designing and conducting studies of induction of labour in the future. Core outcome sets for women’s health conditions will all be available on a specialist website run by the CROWN (CoRe Outcomes in WomeN’s health) initiative.

Useful Information and References

CROWN (CoRe Outcomes in WomeN’s health) initiative. www.crown-initiative.org; COMET (Core Outcome Measures in Effectiveness) www.comet-initiative.org; NICE (National Institute for Health and Care Excellence) – Inducing Labour CG70 www.nice.org.uk

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