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DO YOU WISH TO TAKE PART IN THE OPTION STUDY, A NATIONAL STUDY ABOUT INDUCTION OF LABOUR?

# optionstudien.se

Parents-to-be throughout Sweden are being asked to take part in this research study, whereby women are randomly assigned to receive induction at home or in hospital during the ripening phase of the cervix.

The first step of labour induction takes place in hospital, after which you will be randomly assigned either to remain in hospital and await the ripening of the cervix and the start of active labour (current clinical practice), or to go home, await the ripening of the cervix and the start of active labour and then to return to hospital to give birth.

The objective of the study is to find out whether it makes any difference to the child, the woman, or her partner to wait for the cervix to ripen and labour to begin at home or in hospital. In particular, the study will examine whether both methods of inducing labour are equally safe and how the parents-to-be experience induction.

When the cervix is unripe, it can take several days from induction to the start of active labour. This phase of induction is equivalent to the latency phase in case the labour starts spontaneously, and the pregnant woman is usually at home.

In Sweden, pregnant women whose labour has been induced have hitherto been in hospital. In several other countries, including Denmark, Finland and the United Kingdom, so-called home induction (induction in hospital, await ripening of the cervix and start of active labour at home) is already offered in clinical practice, and some smaller studies around the world show promising results. The majority of all Swedish delivery wards are now taking part in the OPTION study.

## HOW DOES INDUCTION OF YOUR LABOUR AND RANDOM ASSIGNMENT TAKE PLACE?

First, a check is performed (blood pressure, temperature, ultrasound and CTG) to ensure that you and your baby are well. Induction is started either using a tablet that you swallow or by placing a balloon catheter inside your cervix. You and your doctor will choose the method together. Following this, you and your baby will be checked again and, if all is well, you will be randomly assigned either to remain in hospital or to go home (or stay at a patient hotel) and continue your treatment at home.

Home induction: If you have been randomly assigned to go home and labour has been induced using tablets, you will receive a schedule showing when you need to take further tablets (take 1 tablet every 2 hours up to 8 tablets over 24 hours).

If you have been given a balloon catheter, it may remain in place for up to 24 hours.

You will have the opportunity to contact a midwife at the Delivery Ward by telephone at any time, i.e., 24 hours a day. Once the birth starts, either with labour or your water breaking, or if something unexpected occurs, e.g., if you develop a high temperature, you can call the midwife at the Delivery Ward. Once the active stage of the birth starts, or the midwife at the Delivery Ward decides that you should return to the hospital, you will return to the hospital and give birth there. If the birth has not started after 24 hours, you will be given a follow-up appointment at the hospital for a further assessment.

Induction in hospital: If you have been randomly assigned to remain in hospital and labour has been induced using tablets, you will receive 1 tablet every 2 hours up to 8 tablets over 24 hours.

If you have been given a balloon catheter, it may remain in place for up to 24 hours.

You will remain and complete the delivery in hospital.

*You may end your study participation at any time without further explanation. In that case, active labour and the start of the birth will be awaited in accordance with clinical practice at the hospital.*



## CAN YOU TAKE PART?

Pregnant women can take part in the OPTION study if, together with a doctor, they have planned to have their labour induced and their cervix is unripe, i.e. it is not possible to induce labour by rupturing the fetal membranes. You must be expecting one child (not twins) and be between 18 and 45 years of age at the time of induction. Reasons for induction that require you or the baby to be monitored in hospital will mean that you cannot take part. Partners of pregnant women can take part in the OPTION study if their partner is taking part in the study.

For more details, please see the study website, optionstudien.se.

## HOW IS THE INDUCTION OF YOUR LABOUR AFFECTED?

The same methods of inducing labour are used whether you are awaiting going