



THE SWEPI STUDY: Induction of labour in week 41 of pregnancy compared with induction of labour in week 42 of pregnancy

Information to women who have reached 40 full weeks of pregnancy

You have now reached 40 full weeks of your pregnancy. Below you will find some information and an invitation to take part in a study that is being carried out at a number of hospitals in Sweden.

Background

A pregnancy is estimated to last for 40 weeks. The estimated time of delivery is determined at the time of the routine ultrasound examination carried out around week 18 of the pregnancy. A pregnancy that has lasted for more than 42 weeks, i.e. more than two weeks after the estimated date of delivery, is considered overdue.

Delivery usually starts of its own accord but is sometimes 'helped on its way'. This is called induction. At present, when the delivery does not start spontaneously, the time of induction varies among clinics in Sweden and other countries. The time of induction varies between week 41 and week 42 of the pregnancy. This variation is due to a lack of knowledge regarding the best time for mother and baby for the induction of the delivery.

Purpose of the study

The purpose of the study is to investigate the best time for mother and baby for the delivery to be induced where a pregnancy has lasted for more than 41 weeks.

How the study will be carried out

If you wish to take part in the study, you will be randomly assigned to one of two groups: group A or group B. In group A, delivery will be induced in week 41 of the pregnancy (+ 0–2 days), and in group B induction will take place in week 42 of the pregnancy (+ 0–1 days). Induction will be carried out using one of the methods routinely used at your clinic. The method chosen will depend on the consistency and length of the vaginal part of the cervix, and the degree to which it is open (dilated).

Methods for inducing delivery

Delivery can be induced using one of the following methods:

- Inserting a catheter with balloon into the uterus via the vagina
- Inserting a gel or tampon containing the hormone prostaglandin into the vagina
- Swallowing a prostaglandin tablet dissolved in water
- Making a hole in the amniotic sacs (also called artificial rupture of the membranes or amniotomy)
- Administering the hormone oxytocin via a drip

Below you will find a description of the various methods.

A. The cervix is 'unripe'

If the cervix has not started to open or shorten so that it is possible to rupture the amniotic sacs, it is 'unripe'. In this case, one of the following methods will be used:

1. Catheter with balloon

The doctor inserts a thin catheter through the vagina and then feeds it upwards into the uterus. In the top of the catheter there are one or two balloons, which are filled with fluid. The catheter is secured to the inside of the thigh and stretched at regular intervals. When the cervix is 3–4 cm dilated, the catheter and the filled balloon usually fall out of the vagina of their own accord. It is then possible to rupture the amniotic sacs so that the amniotic fluid starts to run out. If the catheter does not fall out by itself, it may be left there for 10–24 hours. The doctor will then decide how to proceed with the induction.

2. Prostaglandin gel or tampon

The doctor or midwife inserts the gel well into the vagina. The aim is to make the cervix softer and shorter so that holes can be made in the amniotic sacs. Six hours after the hormone gel has been inserted into the vagina, the cervix is examined once again to check its degree of ripeness. If it has not opened or shortened, a new dose of gel is inserted into the vagina. A further treatment can be given after 6 hours. Another way of applying hormones in the vagina is to use a tampon-like insert that secretes prostaglandin for 24 hours. The tampon is removed once the contractions have begun.

3. Prostaglandin tablet

The tablet is dissolved in water and then swallowed. This is repeated every two hours until labour pains begin, six to eight times a day.

B. The cervix is 'ripe'

If the vaginal part of the cervix is shortened and is 2–3 cm dilated, it is 'ripe'. The doctor or midwife can then rupture the amniotic sacs (amniotomy).

1. Amniotomy

If the vaginal part of the cervix is shortened and is 2–3 cm dilated, the doctor or midwife can rupture the amniotic sacs so that the amniotic fluid runs out. This stimulates the uterine contractions. If the contractions have not started after 1–2 hours, a drip containing the hormone oxytocin is administered in the arm in order to stimulate the uterine contractions.

2. Oxytocin drip

When the amniotic fluid has gone and the contractions do not start spontaneously, an oxytocin drip will be started (see above).

How is the baby's well-being checked during induction?

Irrespective of the method of induction used, the baby's heartbeats are monitored before, and at regular intervals during, the induction. The delivery is always monitored using CTG and sometimes using foetal ECG (STAN).

Assessment of the handling of the delivery

In accordance with standard procedure for a delivery, your midwife will document the course of the delivery and provide information about the baby in your records.

Are there any risks involved in taking part in the study?

There is currently no study of sufficient size that has assessed the risks of inducing delivery in a pregnancy that has lasted for more than 41 weeks. Even though the timing of the induction of your delivery may differ from the standard procedure at your delivery clinic, your delivery will be handled in accordance with your delivery clinic's existing guidelines. In other words, the same methods will be used, for example, for inducing and monitoring the delivery. If your delivery is induced you will remain at the hospital, which may lead to a longer hospital stay than if the delivery started of its own accord.

Are there any advantages to taking part in the study?

Other women whose pregnancies last for more than 41 weeks may benefit from the knowledge we gain from the study.

What happens if you do not wish to take part in the study?

If you do not wish to take part in the study, you will receive the standard care provided by your delivery clinic, which means induction in week 42 of pregnancy + 0 days.

Handling of data and confidentiality

The study material will be kept for 10 years to facilitate reviews. No unauthorised persons will be able to access it. When the data from the study is published, it will not be possible to identify individuals.

Responsibility for personal data

The hospital's Personal Data Compliance Officer is responsible for processing your personal information. You may contact the Personal Data Compliance via the hospital switchboard.

Insurance

All those who take part in the study are covered by the hospital's patient injury insurance.

Voluntary participation

Your participation is voluntary and you are fully entitled to withdraw from the study at any time without stating a reason. If you choose to discontinue participating in the study, this will not affect your care.

What you need to do if you wish to take part in the study

If you would like to participate in the study, you should contact your midwife at the antenatal clinic. She can clarify the information and answer questions about the study.

How do you find out information about the results of the study?

If you would like to know the results of the study, you are welcome to contact the midwife or doctor responsible for the study at your hospital.

People responsible for the study

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THE SWEPI STUDY

Consent form

I have read the information and I have had the opportunity to ask additional questions concerning the study. I am aware that my participation is voluntary and that I may cease taking part at any time and without stating a reason without this having any effect on my care.

Date, signature: _____

Personal ID number, 10 digits: _____

Print name: _____

Telephone/mobile no.: _____

Email: _____

The undersigned researcher has gone through and explained the purpose of the SWEPI study to the above trial subject and has obtained the trial subject's consent. The trial subject has been given the information to participants.

Date, signature: _____

Print name and job title:
