Scientific title:

The SAINT study: SAfe INduction of labor Trial

A randomized placebo-controlled multicenter trial to assess efficacy of bicarbonate and butylscopolamine bromide for improved induction of labor in first births.

Sometimes induction of labor is necessary. It is performed in every fourth pregnancy in Norway. Induction of labor is recommended when it is considered less a risk for mother/child to bring forward labor than to continue the pregnancy. Reasons can be preeclampsia, diabetes, post-term pregnancy, prelabor rupture of membranes and other conditions. Induction of labor can increase the risk of operative delivery (vacuum, forceps or cesarean section). A Norwegian study from 2020 showed that more than four of ten women with induced labor deliver by caesarean section or forceps/vacuum. Thus, interventions that may improve the safety of induced labor are highly warranted.

In this study, we want to examine if the use of two known medications can reduce the risk of operative delivery after induction of labor. Buscopan can promote dilation of the cervix during labor, whereas bicarbonate can prevent build-up of lactic acid and subsequently counteract the decrease in force of uterine contractions during labor.

Both buscopan and bicarbonate have been used separately in small studies in order to shorten labor. However, no studies have included women with induced labor or have attempted to treat women with both drugs.

The study will be open for participation from 12th Dec 2022 to 12th Dec 2024

You can tell your midwife or doctor if you are interested in participating in this study.

You can participate if:

- You expect your first child
- You are between 18-50 years of age
- You have a single fetus in a cephalic position
- It has been decided that your labor will be induced

A few diseases or conditions in you or your fetus may exclude you from participating in this study, this includes:

- Heart disease
- Glaucoma
- Myasthenia gravis
- Kidney disease

The SAINT study is national, and will take place in 9 hospitals spread around Norway.

We will include and randomize 3000 primiparous women who will have their labor induced.

You will randomly be assigned into one of four treatment groups with 750 women in each group. You as participant and the personnel treating you will not know which group you are in.

The four groups are:

1. buscopan and bicarbonate
2. buscopan and placebo
3. placebo and bicarbonate
4. placebo and placebo

Every participant recieves all the usual treatment when inducing labor. As a participant, you will not miss any of the usual treatment. We will take a routine blood sample before induction. The study-specific treatment starts in active labor. One dose of the study medications is given at the start of active labor (four tablets taken orally and an IV injection through a venous catheter). A new dose of study medications (the same combination as mentioned) will be given four and eight hours later, if you still are in labor.
We will monitor you and your fetus` wellbeing.
All participants will be sent an electronic questionnaire regarding the birth-experience four to six weeks after labor.

Note:

We will take a routine blood sample before induction
A venous catheter will be placed in your arm

Known side effects of the medication being tried in this study are:

- Dry mouth
- Tachycardia
- Dizziness

The medications have been administered to many women without any severe side effects