

Invitation to first-time mothers

The EVA-trial: Lateral Episiotomy in Vacuum Assisted Delivery

Hello first-time mother!

In this leaflet, you are invited to participate in a medical research trial investigating how to avoid large perineal tears during vacuum assisted delivery.

Sometimes it is necessary to assist the delivery by using a ventouse suction cup (vacuum assisted delivery). During this type of delivery, it is slightly more common to experience larger tears in the area between the vagina and anus (the perineum), which can involve the anal muscles.

EVA stands for Episiotomy in Vacuum Assisted delivery.
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The purpose of this trial is to investigate if it is better to proactively cut (lateral episiotomy), or to leave the perineum to possibly tear spontaneously. The overall aim is to study how larger tears involving the anal muscles can be avoided during vacuum assisted delivery.

What will we be doing?

By intentionally cutting we aim to redirect the tear away from the anal muscles.

However, a cut can be more painful than a spontaneous tear whilst healing. Therefore, we would like to ask you, if you require a vacuum assisted delivery, would you consider joining a trial in which you would be randomly selected to undergo a lateral episiotomy (a cut) or a delivery with no cut, but the potential of a spontaneous tear?

Random selection is a scientific method used to avoid selection errors when dividing patients into separate treatment groups.

If you do require a vacuum assisted delivery you will always receive pain relief. Before a cut an additional local pain relief is given to numb the area around the vagina. If you are randomly selected for a lateral episiotomy this will be performed as the baby's head is being delivered by making a small diagonal cut from the vagina and out to one side. Most women do not feel the cut and do not experience any difference compared to having a spontaneous tear.

All patients will receive the same perineal support to avoid tearing. This means we will manually support the perineum and guide you during your contractions. After delivery, everyone will be properly examined and any cut or tear will be repaired. Larger tears are always repaired in the operating theatre by an experienced doctor.

How will we follow up?

Regardless of which group you belong to, you will receive equal care and follow up.

During the follow up we will collect data from your medical records and from registers

regarding the delivery and if there were any complications to you or the baby. You will receive questionnaires on the postnatal ward, 2 months, and 1 year after delivery. The questions cover urine and bowel issues as well as sexual function, quality of life, and your childbirth experience. The questionnaires will take 5-10 minutes to complete. You will be offered a follow up visit at 6 months after the delivery. We will also contact you for a follow up at 5 years after delivery.

Your integrity and safety

Participation is voluntary. It will not affect your care if you choose not to participate. If you decide to participate, your answers are important regardless of whether you experienced complications or not. We aim to improve care during childbirth, specifically during vacuum assisted delivery, and to improve the long-term health and wellbeing of women. Therefore, we need information about your experiences.

Your answers from the questionnaire are kept confidential. They will only be available to the research group (find details below) and will not be included in your medical records. The answers are anonymous and can only be linked to your personal data by the research group. An independent investigator may review the research and will in that case require access to the original data, including medical records and questionnaire answers. The investigator will treat all data as confidential information.

The medical data and questionnaire answers will be reported as a group so your participation will not be visible in the study results.

If you wish, you can receive the result from the study when it is published. All data will be kept for 10 years before it is destroyed. Once per year you can request information about your personal data. Please contact us for more information. Your hospital is legally responsible for the personal data in this trial.

Thank you for your time and consideration to participate!

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Informed Consent Form

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I agree to participate in the EVA-trial, if I would need a vacuum assisted delivery. I know that participation is voluntary and I can at any time change my mind. If I choose not to participate in any part of the follow-up, it will not affect the medical care I receive.

Signature

Date

Name

Place

”Personnummer”

E-mail (also after delivery)

Mobile number (also after delivery)

Signature of researcher/informer

Date

Name of researcher/informer

Clinic/Place

Please hand the consent form to your midwife, who will send it to the responsible investigator at your hospital. The midwife will make a note in your Obstetrix record. You can also bring the consent form along to the delivery ward when it is time to give birth.