WHAT HAPPENS TO THE INFORMATION COLLECTED?

This project will collect information from the records about the mother and your child. Information regarding the mother's age, weight, height, number of previous pregnancies, information regarding the current pregnancy, as well as the delivery, and what happens to the baby, will be collected from the Swedish Pregnancy Registry, the delivery record and, when applicable, from the patient chart from the neonatal ward. Your responses and results will be processed so that unauthorized persons may not access them. The data collected will be coded and processed only by those who are responsible for the study. Independent quality assessors may also access the information. The code key will be kept in a secure location and will only be accessible to the study team. The information is subject to secrecy, pursuant to the Public Access to Information and Secrecy Act (2009:400).

The purpose for processing these personal data is research, and the legal basis is that you have given your consent to taking part in the study. The mother's personal information will be stored during the period that the study lasts, and until data processing is completed. Personal data will be kept on file for ten years after the storage period, pursuant to the Archives Act (1990:782) and Region Skåne's regulations for archive and information processing.

Region Skåne is responsible for your personal data. Pursuant to the EU General Data Protection Regulation (GDPR), you have a right to access the information about you that is being processed as part of this study, free of charge, and where necessary, have any errors corrected. You may also request that the data about yourself be deleted, and that the processing of your personal data be restricted.

If you wish to access the information, you shall contact Ola Andersson, who is the researcher in charge of the project (see contact information, below).

The Data Protection Officer is reached at the following address: "Dataskyddsombudet, Region Skåne, 281 89 Kristianstad". If you are dissatisfied with the manner in which your personal data are being processed, you are entitled to submit a complaint to the Swedish Data Protection Authority (Datainspektionen), which is the regulatory authority.

IF YOU WISH TO OBTAIN ADDITIONAL INFORMATION, YOU ARE WELCOME TO CONTACT ANY OF US AT SKÅNE UNIVERSITY HOSPITAL IN MALMÖ

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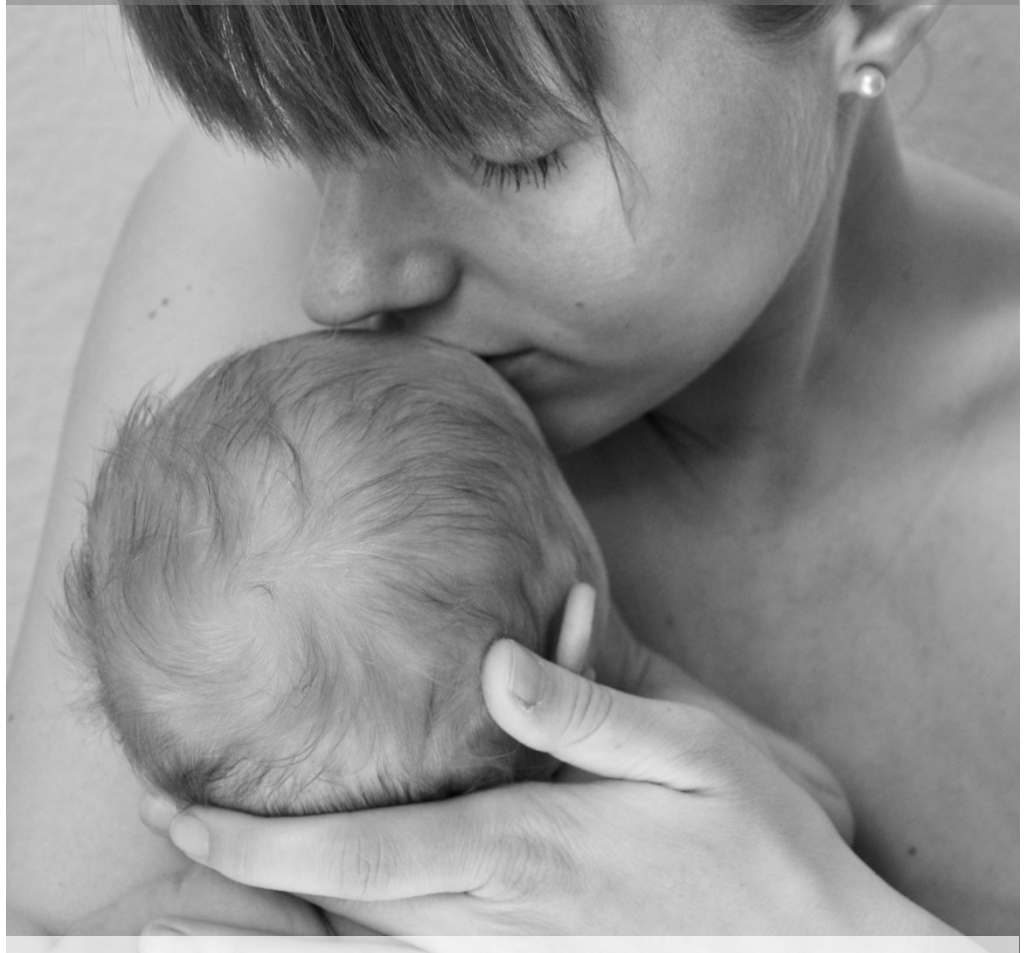
Version 20201112

The SAVE Study

SUSTAINED CORD CIRCULATION AND VENTILATION



Information for parents

Information to research participants

We would like to ask you whether you and your newborn would like to take part in a research project. This document contains information for you about the project, and what participating in it would entail.

WHAT KIND OF PROJECT IS THIS AND WHY DO WE WANT YOUR BABY TO PARTICIPATE IN IT?

In Sweden, almost one in ten babies needs some kind of measure taken so they can start to breathe normally. In many cases, the baby has, for a shorter or longer time, a affected blood circulation in the placenta or the umbilical cord. Currently, if the baby, when born, exhibits insufficient respiration or does not exhibit any signs of life, the umbilical cord is cut immediately, and the baby is moved to a location where artificial respiration /ventilation can be administered, as well as other measures taken to help the baby recover. This is called neonatal resuscitation, or in Swedish, HLR (heart-lung rescue).

For full-term, healthy babies, the routine at the majority of Swedish delivery wards up until 2008, had been to cut the cord within 30 seconds after birth. Several studies have later shown that by keeping the umbilical cord intact for three to five minutes, a good deal of the blood volume that is left in the placenta may be transferred to the newborn baby. This has a positive effect on the baby in the form of reduced incidence of anaemia and iron deficiency and, in general, satisfactory development, without any observable disadvantages.

The above-mentioned studies have not included babies who have needed neonatal resuscitation. It is most probable that the blood that remains in the placenta is rich in both oxygen and nutrients. There is a possibility that babies who are born with oxygen deficit may benefit from this additional oxygen and nutrients if the umbilical cord is left intact for a few minutes.

This matter, however, has only been researched in a few pilot studies.

We wish to study what happens if the umbilical cord is left intact for at least three minutes during ongoing neonatal resuscitation, compared to the current practice of cutting the umbilical cord before commencing neonatal resuscitation. We will be asking 8,000 expectant parents and estimate that about 600 children will require neonatal resuscitation.

HOW IS THE STUDY CONDUCTED?

Immediately before birth, your baby will be randomly assigned, in the event neonatal resuscitation is needed, either to have neonatal resuscitation with an intact umbilical cord, performed next to the mother, or to have the umbilical cord cut immediately, with neonatal resuscitation performed on an adjacent resuscitation table.

The equipment and the staff who administer the neonatal resuscitation are the same. The only differences are whether the umbilical cord is intact or not, and the place where the resuscitation is performed. Depending on the needs of each baby, a baby needing neonatal resuscitation may be cared for either on the delivery and obstetrics ward or on the neonatal ward. On the delivery and obstetrics ward, the baby's general wellbeing and blood sugar are monitored according to existing routines. Babies that need more monitoring and additional investigation will be cared for in the neonatal ward.

HOW IS THE STUDY CONDUCTED? (CONTINUED)

In addition to what is routinely done in care and treatment, we will be noting your baby's breathing more carefully at one hour of age regardless of whether your baby is in the delivery and obstetrics ward or in the neonatal ward.

Those babies who have needed neonatal resuscitation and are included in the study will be followed up with the help of a questionnaire regarding the child's development that the parents will complete after 4 and 12 months. This is a follow-up beyond what is routine. The mother will receive questionnaires about breastfeeding and attachment.

Those babies who have displayed signs, during their time in hospital, of injury from lack of oxygen, will be called for a routine follow-up at 2 and 5.5 years of age. We will include the results of this follow-up in the SAVE-study.

POSSIBLE CONSEQUENCES AND RISKS OF PARTICIPATING IN THIS STUDY

Performing neonatal resuscitation on a baby with an intact umbilical cord when the baby is near its mother is something that the staff taking care of the baby may not be used to. All staff will therefore receive training in this prior to the start of the study. Those babies who have neonatal resuscitation begun while they have an intact umbilical cord may receive an increased amount of blood from their placenta. This extra blood may lead to a speedier recovery and a better blood count, which, in turn, can prevent future anaemia, but may also possibly increase the risk of jaundice. Breathing may be affected both positively, with improved oxygenation, and negatively, with faster and more laboured breathing.

Babies who need neonatal resuscitation in connection with their birth, and who have been exposed to serious oxygen deprivation, run a greater risk of injury as a result of this, in the form of damage to the brain, heart, kidneys, etc. A result of taking part in this study is that your baby will be monitored with respect to his or her development at the age of one year. Your baby will not be subjected to any pain or discomfort as a result of this study.

PARTICIPATION IN THIS STUDY IS VOLUNTARY

Your participation in this study is voluntary, and you can choose to terminate it at any time. If you choose to terminate your participation, you are not required to give any reason, and it will not affect you or your child's care and treatment.

If you wish to terminate your child's participation, you shall contact the person in charge of this study (see the back of this folder). The legal entity responsible for this research study is Region Skåne. In Swedish, such an entity is called the "forskningshuvudman". The insurance coverage that patients have in the healthcare system also applies to the babies that take part in this study.

HOW DO WE OBTAIN INFORMATION REGARDING THE RESULTS OF THIS STUDY?

Information regarding the results of this study will be sent to those parents who have furnished their e-mail address. These results will also be published on websites, social media platforms, scientific conference documents, scientific periodicals, and will be communicated to the media as news. The results of individual babies will not be distributed, nor will they be possible to ascertain.