Are there any risks to my baby or me?

The fetal monitor used in this study has been approved by the Food and Drug Administration. There is a possibility of discomfort during the placement and adjustment of the monitor for the mother. Other possible risks include a skin mark, infection and/or bleeding of the baby’s scalp where the monitor is placed.

Will it cost anything to participate?

No. All research related procedures will be provided at no cost to you. The use of the fetal STAN monitor will also be provided at no cost.

You will receive a $50 gift certificate for your participation. Time commitment will be from the placement of the monitoring system until delivery of your baby.

Who is conducting the study?

This research is funded by a grant from the Eunice Kennedy Shriver National Institute of Child Health & Human Development (NICHD).

At the University of Texas Health Science Center at Houston, Dr. Sean Blackwell is the Principle Investigator of the study. He can be reached by phone (713-500-6415) or by e-mail (Sean.Blackwell@uth.tmc.edu).

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What is the purpose of the study?

The purpose of this study is to determine if the STAN monitor can give us information we need to better determine which unborn babies cannot tolerate labor. This study is for mothers who:

- Have a singleton (one baby) pregnancy
- Are cephalic (head down presentation)
- Are planning to have a vaginal delivery
- Are at least 36 weeks 1 day

What is the Fetal STAN Monitor?

The Fetal STAN monitor is an electronic fetal heart rate monitor which is used in addition to the existing electronic fetal monitor during pregnancy. The STAN monitor specifically looks at the electrical activity of your baby’s heart and is designed to help your doctor determine how well your baby is doing in labor. The STAN monitor is routinely used in Europe and in many hospitals across the U.S. The monitor is approved by the FDA (Food and Drug Administration) for use in the United States.

What is masked or unmasked?

Enrolled women will be randomly assigned to a masked or unmasked group which determines how the STAN monitor is used by the doctor/nurses. If masked, the STAN information will be stored on a computer and not be made available to the physician. The physician will proceed in the usual fashion and manage the labor using the conventional monitoring. If unmasked, the physician will have access to both monitoring systems to assess the well being of the baby.

What do I have to do?

If you meet the study requirements, you will be asked to participate in the study.

If you consent to the study, your care will be managed by your doctor and you will be monitored by our research team until delivery of your baby.

A fetal scalp electrode will be placed on your baby’s head through the cervix after your water breaks. Another small electrode will be placed on your leg with a piece of tape.

After you deliver your baby, a study nurse will obtain some relevant information regarding the birth. Additionally, the research team will collect information from the umbilical cord blood gas taken at the time of birth.

You will be compensated for your participation.

IRB NUMBER: HSC-MS-09-0363
IRB APPROVAL DATE: 4/21/2010