Information for Potential Study Candidates

A National Institute of Child Health and Human Development (NICHD) sponsored study of prenatal and postnatal closure of myelomeningocele of the Maternal Fetal Surgery Units Network; a collaboration of The Children's Hospital of Philadelphia, the University of California at San Francisco, Vanderbilt University Medical Center in Nashville and the George Washington University in Washington, D.C.

For Information Call Toll Free
1-866-ASK-MOMS (1-866-275-6667)
www.spinabifidamoms.com

Introduction

Myelomeningocele, also known as spina bifida, is a birth defect affecting one in every one thousand pregnancies in the United States. Although the causes of spina bifida are not well understood, doctors believe that both genetic and environmental factors play a role. During the first 28 days of a pregnancy, the brain and spinal cord form in the developing baby. When normal development of the spinal cord is interrupted, spina bifida results. The majority of babies with spina bifida have a variety of medical problems including some amount of paralysis of the lower part of their body (this ranges from very mild to quite severe), loss of control of their bowels and bladder, and abnormalities of the brain.

For decades the standard treatment has been to close the spinal defect soon after the baby is born. This is called *postnatal surgery*. Recently doctors have developed an experimental operation performed while the baby is still in the mother's womb. This is called *prenatal surgery*. Prenatal surgery may improve the outcome of babies born with spina bifida.

MOMS

The MOMS (Management of Myelomeningocele Study) is a special type of research study called a *clinical trial*. It is designed to compare prenatal with postnatal surgery in an effort to find out if either treatment is better. At the present time, doctors do not know which type of surgery is best. The National Institute of Child Health and Human Development (NICHD), a part of the National Institutes of Health (NIH), has sponsored this cooperative study between The Children's Hospital of Philadelphia in Philadelphia, Pennsylvania, the University of California at San Francisco in San Francisco, California, and Vanderbilt University Medical Center in Nashville, Tennessee. Each of these hospitals has a Maternal Fetal Surgery Unit with extensive experience in prenatal surgery and is a designated MOMS Center.

Two hundred (200) women carrying a baby with spina bifida will be enrolled in the study. Half will be put into the group to have prenatal surgery and half in the group to have postnatal surgery. This is a *randomized* trial which means that neither the doctors involved in the study nor the women participating in the study will be able to choose who has prenatal and who has postnatal surgery.

Women will be assigned to a particular MOMS Center based on geographic location and the need to divide the study participants evenly between the three centers. Prenatal surgery will be done at the assigned center between 19 and 25 weeks of pregnancy. Deliveries for both groups will be performed by C-section at the assigned MOMS Center at approximately 37 weeks of pregnancy. The infants in the postnatal surgery group will have their spina bifida closed at the MOMS Center as soon as possible after delivery, usually within 48 hours.

Medical information on the mothers and babies will be gathered throughout the study and follow-up of their progress will continue until the child reaches at least two and a half years of age. Analysis of this information will help scientists determine if the prenatal or postnatal surgery is better for infants with spina bifida.

How to Qualify for MOMS

To enroll in the study

You must be:

- Carrying a baby with spina bifida that is not too high or too low on the back
- At least 18 years old
- Available to have the prenatal surgery between your 19th and 25th week of pregnancy
- A resident of the United States

Your baby must have:

- The Chiari II malformation, a problem with the brain commonly found in those with spina bifida
- Normal chromosomes

You will not be able to enroll in the study

If you:

- Are carrying more than one baby
- Have insulin dependent diabetes mellitus
- Have a history of spontaneous delivery before 37 weeks
- Have a history of an incompetent cervix, a short cervix, or planned cerclage in this pregnancy
- If the placenta is covering any part of the opening to your womb or if you have had significant bleeding within the last few weeks
- Have HIV/AIDS, hepatitis B or hepatitis C
- Have problems with your uterus such as several large fibroids
- Are obese (have a body mass index more than 35: your doctor can check this)
- Have medical problems which would increase the risks of surgery and/or anesthesia
- Would have significant difficulty with the emotional aspects of participating in this type of study
- Do not have a support person to accompany you for the necessary evaluations, operations and follow-up visits
- And your baby have certain blood incompatibilities

If your baby has:

- Any abnormality not related to the spina bifida
- Severe kyphosis (a type of curvature of the spine)

Risks of Prenatal Surgery

For the mother:

- All of the risks associated with any operation such as infection, bleeding, and problems associated with anesthesia or medications used

- Infection of the uterus developing during the prenatal surgery
- Significant leak of amniotic fluid following the prenatal surgery
- Prolonged hospitalization following the prenatal surgery
- Loss of the ability to have more children
- The need for C-sections for all future deliveries

For the baby:

- Preterm birth
- Side-effects from the drugs used in the mother before, during and after the prenatal surgery
- Further damage to the spinal cord occurring during the prenatal surgery
- Separation between the uterus and the membranes surrounding the baby
- Fetal or newborn death
- Worsening of the medical problems associated with spina bifida between the time of prenatal surgery and birth

Risks of Postnatal Surgery

For the mother

- All of the risks associated with C-sections done for any other reason including bleeding, infection and problems with the anesthesia or medications used

For the baby:

- Risks associated with closure of a myelomeningocele defect such as damage to the spinal cord, infection, bleeding and the usual risks of surgery and anesthesia

Costs of participating in the study

There will be no additional costs to you beyond those you would normally have for obstetrical care and delivery given that you are carrying a baby with spina bifida. It may be that you do not have health insurance. For women who do have insurance, individual insurance policies vary. Costs you may be responsible for include co-payments and deductables. The MOMS Center staff will work with your insurance company. In addition, the study will cover all travel, meal and lodging costs for you, a support person and (for follow-up visits) your baby.

If you are interested in finding out more about this study speak with your doctor or call 1-866-ASK-MOMS to speak with the MOMS Study Coordinator.