



# Information for Families

# MOMS

Management of Myelomeningocele Study

The Management of Myelomeningocele Study (MOMS) is a special type of research study called a randomized clinical trial. In an effort to determine the best treatment for babies with a birth defect known as spina bifida, MOMS is designed to compare prenatal surgery (before birth) with postnatal surgery (after birth). At the present time, the medical community does not know which type of surgery is best for babies with spina bifida.

**MOMS is a research study conducted by:**

**The Children's Hospital of Philadelphia,  
Vanderbilt University Medical Center,  
University of California San Francisco,  
and The George Washington University,  
in collaboration with the  
Eunice Kennedy Shriver  
National Institute of Child  
Health and Human Development**

## Spina Bifida

Myelomeningocele, also known as spina bifida, is a birth defect that occurs early in pregnancy. The neural tube that forms the spinal cord does not fully close and leaves an opening in the baby's back. Spina bifida is a lifelong disability and it often leads to serious medical problems, including paralysis of the lower part of the body, loss of bowel and bladder control, abnormalities of the brain, and learning disabilities.

## Postnatal Surgery

For many years, the standard treatment for babies with spina bifida has been postnatal surgery. This type of surgery involves closing the spinal opening as soon as possible after a baby is born. This surgery is not a cure for spina bifida, but is very important for the babies for many reasons, including helping to protect the exposed spinal cord and preventing infection.

## Prenatal Surgery

In recent years, doctors have developed an experimental operation for spina bifida known as prenatal surgery, which is done in the same way as postnatal surgery, but it is performed earlier, while a baby is still in the mother's womb during pregnancy. Like postnatal surgery, prenatal surgery is also not a cure for spina bifida, but it is possible that prenatal surgery may help babies with spina bifida.

**Please call for more information  
1-866-ASK-MOMS**

## Contact Us

Women carrying a baby with spina bifida, their health care providers, or their family members may call us at **1-866-ASK-MOMS** to begin the enrollment process or simply to ask for information. We can explain the study in detail, including the requirements and risks and benefits of participating. We are also happy to answer any questions about spina bifida.

**MOMS – Management of Myelomeningocele Study**

**1-866-275-6667 phone**

**[www.spinabifidamoms.com](http://www.spinabifidamoms.com)**

**1-866-458-4621 fax**

# A randomized clinical trial designed to compare prenatal and postnatal surgery for spina bifida

## Locations

The women who participate in MOMS are assigned to a particular MOMS Center based on geographic location and the need to distribute the participants between the three MOMS Centers:

- The Children's Hospital of Philadelphia
- Vanderbilt University Medical Center
- University of California San Francisco

## Screening

After a review of medical records, the woman and a support person of her choosing travel to the assigned MOMS Center for a comprehensive medical evaluation and the opportunity to meet with the MOMS team of specialists to have all of her questions answered.

## Enrollment

A total of 200 women carrying a baby with spina bifida will be enrolled in the study. At the MOMS Center, each woman who decides to participate is randomly assigned, like the toss of a coin, to either the prenatal surgery group or the postnatal surgery group. Therefore, each woman has an equal chance of receiving prenatal surgery or postnatal surgery. Because MOMS is a randomized trial, neither the doctors and staff involved, nor the women who participate, will be able to choose who has prenatal surgery and who has postnatal surgery.

## Research

Medical information about the women and babies in the study is gathered throughout the pregnancy and continues until the child reaches at least two and a half years of age. This information will help doctors and families learn if prenatal surgery or postnatal surgery is better for babies with spina bifida.

## Treatment

For the women in the MOMS prenatal surgery group, the surgery is done at the assigned MOMS Center between 19 and 25 weeks of pregnancy. The babies in both the prenatal surgery group and the postnatal surgery group are delivered at the assigned MOMS Center by C-section at about 37 weeks of pregnancy. The surgery for the infants in the postnatal surgery group is performed at the MOMS Center as soon as possible after birth.

## Requirements for Participants

### The woman must be:

- carrying a baby with spina bifida (myelomeningocele)
- at least 18 years of age
- a legal resident of the United States
- between 19 and 25 weeks of pregnancy

### The baby must have:

- spina bifida that is not too high or too low on the spine
- hindbrain herniation (Chiari II malformation)
- normal chromosomes by CVS or amniocentesis
- no other problems unrelated to spina bifida

### The woman may not enroll if she:

- is carrying more than one baby
- has medical problems that increase the risks of surgery
- has a high risk of having a premature baby
- has no support person able to stay with her at all times while at the MOMS Center

## Costs

Travel and housing arrangements are paid for by the study. In addition, there are no additional medical costs beyond those the woman would normally have for obstetrical care and delivery, given that she is carrying a baby with spina bifida.