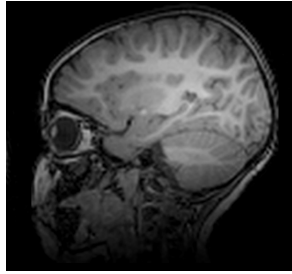


MEMORIAL HOSPITAL ADVANCED BABY IMAGING LAB

We are inviting families to participate in a Memorial Hospital of Rhode Island research study of Brain Development during infancy and early childhood.

The study's goal is to determine the effect of early life nutrition on brain and cognitive development in the first 24 months of the infant's life. The study involves the mother completing self-reported questionnaires and undergoing a brief cognitive assessment. The study also involves taking pictures of the infant's brain while asleep (natural sleep, no sedation), using a magnetic resonance imaging (MRI, generally safe and non-invasive) scanner, coupled with evaluations of his/her functional development, like language and motor control.



Two nutrient blends in infant formulas will be evaluated in comparison with a reference group of breastfed infants.

If you are not breastfeeding, your infant will be randomized into one of the study infant formula groups. Randomization means your infant is put into a group by chance. Your infant will have an equal chance of being placed in either group. You will receive a nutritional product (infant formula) and you will be asked to provide it to your baby up to 12 months of age and according to her/his appetite. Solid food will be introduced during this first year of life according to infant feeding guidelines.

If you are breastfeeding, you may continue providing your breast milk at your convenience. The clinical team will provide you with breastfeeding advice through access to a Lactation Counselor as needed.

ARE YOU BECOMING A MUM ? SOON

CONTACT US

For Further Information, to Book or to Take Part in an Information Session, Please Contact:

Sean Deoni, PhD

Telephone: 401-863-7661 or 401-338-6943

Email: baby.imaging.lab@gmail.com

THIS NUTRITIONAL RESEARCH STUDY MAY INTEREST YOU

**We want to better understand how
early life nutrition impacts brain
development in the first 24 months
of the infant's life**

Full title of the Research Study: The Effect of Myelin-Relevant Nutrients in Infant Formula on Brain Myelination and Cognitive Development.

This study has been reviewed by, and received ethic committee approval.

Version 2.0 - 13 Dec. 2016



WHAT ARE YOU HOPING TO LEARN?

Billions of connected brain cells communicate fast and efficiently thanks to an insulating fat layer called myelin sheath that develops around the fibers. Myelin is critical for normal and efficient brain function and is a crucial element of brain development. The role of nutrition in the process of myelination is not well understood and the purpose of this research is to increase our knowledge in this area.

By better understanding the relationship between nutrients, activity, functional development and myelination, we will be one step closer to developing treatments for infants with developmental disorders

CAN WE (MY BABY AND I) PARTICIPATE?

Yes! If you are pregnant and you are interested in this research. Before your baby begins the study (max 6 weeks of age) you will be asked if you wish to have the baby participate in the study. Your baby should be born at term and be healthy.

WHAT WILL WE GET FROM PARTICIPATING?

In addition to reimbursement for time and travel, you will be provided with a fun DVD of some of your infant's brain images as well as a general assessment of his/ her behavioral functioning compared to other infants in the same age range.

If your infant is on infant formula, you will receive the study infant formula up to 12 months of age at no cost. If your infant is breastfed, you will receive a financial compensation (such as a voucher for books, developmental toys). Additionally, a Lactation Counselor will always be available to you, to provide you with advice in order to facilitate the establishment and continuation of breastfeeding.

WHAT IS INVOLVED FOR MYSELF AND MY BABY?

The study will comprise of 8 visits which will include imaging and functional evaluation sessions over the course of 24 months of your child. Study visits will occur at the Memorial Hospital and the Baby Imaging lab.



For my baby:

- Brain imaging sessions (5 over the course of 2 years). MRI is a safe and painless procedure (max 25 minutes per scan).
- Demographics, medical history and body measurements
- Behavioral assessment and cognitive questionnaires (child's language, vision, and motor control skills). These are assessed via play like activities requiring about 45 minutes.
- Vital signs: weight, height, blood pressure, respiratory rate, temperature and pulse may be checked.
- Few blood collections

For me:

- Demographic and medical history
- Questionnaires related to your mode of baby feeding
- Cord blood collection at delivery (optional)
- Few sample of your breast milk (if breast-feeding ongoing)

PARTICIPANT RESPONSIBILITIES

While you and your infant participate in this research study, you will need to:

- Follow all study procedures (provided by the study team)
- Maintain the same feeding method: continue breastfeeding as long as possible or use the assigned infant formula.
- Attend all study visits within the stated timeframes.

FREQUENTLY ASKED QUESTIONS

IS MRI LIKE AN X-RAY OR CT-SCAN? NO! X-rays and CT scans use ionizing radiation to create an image. MRI does not use ionizing radiation. Instead, MRI uses a strong magnetic field and radio-waves (similar to those of an FM radio) to make images of the brain.

IS MRI SAFE? YES. There is a lot of incorrect information regarding MRI safety available on the internet. After 30 years of clinical and research imaging, no peer-reviewed study has shown any long-term negative effects associated with MRI (usage of no radiation). FDA considers MRI to be a 'non-significant' risk when performed within specified parameters. Our study meets all of these safety measures.

BUT MRI'S ARE LOUD? MRI scanners built for adults can be very loud, reaching more than 140dB (almost as loud as a rock concert). Through the use of sound proofing and special sequence design, we have reduced this to less than 60dB - the same as casual conversation. To reduce noise further, we use noise-attenuating head phones specially designed for infants and toddlers. As a result, infants can sleep through the scan.



CAN I SEE THE SCANNER AND FACILITY, AND MEET THE RESEARCH TEAM BEFORE AGREEING TO PARTICIPATE?

ABSOLUTELY! We can arrange an information session during which you can tour the facility, see the scanner, meet members of the team and get a better idea of how a session will run. You can also ask questions. If you decide to participate, we will go through the consent form with you and arrange a convenient time for the scan.

WHY DO YOU IMAGE MY INFANT WHILE THEY ARE ASLEEP?

Just as taking pictures of a moving object causes blurry photos, moving during an MR scan also causes blurry images. By imaging children (under 4 years of age) while they sleep, we can be sure they will stay still for the whole scan.

DO YOU USE SEDATION TO PUT MY CHILD TO SLEEP?

NO! We schedule scans during normal nap or sleep time. We have private rooms where you and your child can relax and fall asleep. Once asleep, we will move your child into the scanner.

CAN I BE IN THE SCANNER ROOM DURING THE SCAN?

ABSOLUTELY! As long as you have no metal implants, pacemaker, etc., we encourage you to be in the scanner room along with your infant. At least one member of the research team will also be in the room.

WHAT IF I WANT TO STOP?

You can stop at any time. If you are uncomfortable before or during the scan, just alert us and we will stop everything.