Government of South Australia

Children, Youth and Women's Health Service

Child Health Research Institute Inc.

DHA TO OPTIMISE MOTHER INFANT OUTCOME:

THE DOMInO TRIAL

INFORMATION SHEET

You are invited to participate in a study that aims to determine whether increasing the amount of special fat called DHA in the diet of pregnant women reduces symptoms of postnatal depression and is beneficial to infant development.

DHA is an omega-3 fat found in fish and fish oils and is thought to play a role in the way the brain works and develops. It has been suggested that supplementing the diet with DHA may reduce feelings of depression, while studies with young infants suggest that enriching the diet with DHA may also help improve visual development. While in the womb, the baby is supplied with DHA from the mother's circulation. The level of DHA in the mother's circulation is largely determined by the amount of DHA in the mother's diet. Australian women generally have low levels of DHA. This study will help determine whether increasing the amount of DHA in the diet improves outcome for women and their babies.

WHAT DOES THE STUDY INVOLVE?

You will be randomly assigned (like tossing a coin) to one of two groups. One group will be asked to take capsules with DHA (tuna oil) and the other group will take capsules with a blend of vegetable oils (canola, sunflower and palm oils) with no DHA. None of the oils have been genetically modified. Neither you nor the research team will be able to choose which group you are in or know which type of capsule you have been selected to take. You will be asked to take three capsules daily until the day your baby is born.

We have already shown in similar studies that DHA at the dose to be used is safe. The only side effect noted by some women is "fishy burps". At very high doses (12 times higher than the dose in this study) tuna oil may result in a 10% increase in blood clotting time and a 10% decrease in blood pressure, neither of which is considered dangerous.

One third of women enrolled in the study will be randomly selected for their child to participate in a developmental follow-up.

WHAT WILL HAPPEN DURING THE STUDY?

1. At enrolment you will be asked to complete a short questionnaire about the support you have at home.
2. At six weeks and six months after your baby is born you will be asked to complete a short questionnaire about your mood and sense of well-being. If your responses indicate that you may have symptoms of depression, we will ask you to see your General Practitioner.
3. A 5 mL sample of cord blood will be taken at the time of birth to measure the level of DHA.
4. Health information will be taken from your medical records and your baby's medical records.
5. When your baby is 12 months old we will notify you if s/he has been selected to have a developmental assessment. Neither you nor the research team will be able to choose which babies will be selected for the developmental follow-up.

At 18 months of age (if randomly selected or if gestational age is less than 37 weeks)

1. Your baby will have a developmental assessment which will be conducted by a psychologist or paediatrician. This involves a series of activities to see how your baby moves, stands and walks as well as play with puzzles and other toys to look at how your child solves problems. This appointment will take approximately one hour to complete.
2. You will be asked some brief questions about your baby's home environment.
3. You will be given $10 to off-set costs associated with the developmental follow-up visit.

YOUR RIGHTS

You are free to withdraw from the study at any time without any explanation of why you have chosen to do so and without prejudice to you and your baby's treatment.

All information gathered will be treated with confidence and no information that could identify you or your baby will be released to any person not associated directly with the study. These results may eventually be published in medical journals or at professional meetings, but you or your child will not be identified in any way.

ANY QUESTIONS?

If at any time during the study you have any problems regarding appointments or have any other queries, please ring our office on 8161 7458 and leave a message on our answering machine; one of our nurses will return your call as soon as possible. If you have a problem and would like to talk to us immediately please ring 8161 7000 and ask for pager 2599, and one of our research nurses will answer your call.

This study has been reviewed and approved by the Women's & Children's Hospital (WCH) Human Research Ethics Committee. Should you wish to discuss the study with someone not directly involved, in particular in relation to matters concerning policies, information about the conduct of the study or your rights as a participant, or should you wish to make a confidential complaint, you may contact the executive secretary of the Human Research Ethics Committee, Ms Brenda Penny, WCH (8161 6521).