

## THE USE OF FISH OIL FOR ALLERGY PREVENTION

### INFORMATION TO VOLUNTEERS

This study is part of a large research program aimed at preventing asthma and allergic diseases. To do this, it is essential that we understand why there has been a dramatic increase in the incidence of these diseases. Changing factors in the environment, such as diet, may now favour the development of allergy.

There is extensive evidence that the polyunsaturated fatty acids, found in fish oil have strong anti-inflammatory effects, and may suppress allergic immune responses. Unfortunately, “western” diets are becoming more deficient in these substances, and this may be one reason for the rise in allergies. We recently showed that giving fish oil during pregnancy increased levels of omega-3 fatty acids in babies. These infants tended to have less allergic symptoms in their first year of life.

The purpose of this study is to confirm this in a larger group of infants at high risk of allergy (because of a family history of allergies) and to study the immune effects in more detail. In this study we are giving fish oil supplements directly to the baby as an easy way of boosting their levels of anti-inflammatory polyunsaturated fatty acids. We hope to see that fish oil will reduce the risk of developing future allergic responses. We will supply fish oil or a placebo (olive oil) for your baby to take daily for 6 months after birth. This will be given as a small amount of vanilla flavoured oil (from a 650 mg capsule) which can be squirted into the mouth or given by spoon. **This will not interfere with your choice to breast feed.** If you do not breast feed, we will recommend that you use a special (partially hydrolysed) formula to reduce the chance of allergies in your baby.

Fish oil is naturally occurring, inherently safe and is actually promoted as “healthy”. The product used in this study is carefully tested for purity and contamination. Babies will receive either n-3 rich fish oil (650mg fish oil containing 280mg docosahexaenoic acid [DHA] and 110mg eicosapentaenoic acid [EPA]) or placebo (650mg olive oil/day). This amount is based on previous studies which investigated a role of fish oil in allergy prevention in infants and is equivalent to eating a 1/6 adult portion of fish daily.

#### *What this study entails for you:*

1. We will need to see you on only one occasion during your pregnancy. The visit will take 30-45 minutes.
2. We will perform allergy skin testing on you and a single blood test on one (1) occasion during pregnancy. The skin test involves putting drops of fluid containing a small amount of allergen on the arm. The fluid is scratched into the skin and if you are allergic to the substance a small welt will develop within minutes. This is a very safe procedure with only a very small risk of generalized reaction in highly allergic individuals. Blood collection may result in some minor bruising but the risk of long term problems are extremely unlikely. You (and your baby) may also be asked to participate in allergy gene studies and will be given a separate information DNA information sheet and consent form.
3. Cord blood will be collected from the placenta AFTER the baby has been delivered. This blood is normally discarded with the placenta. We will also collect a sample of the placenta for immune studies. We will NOT be taking any blood samples directly from your baby at birth.
4. We request permission to review medical records for information about the delivery and your baby’s health.
5. You will be asked to give your baby a fish oil supplement or placebo once a day until 6 months of age. All these supplements are safe and will be provided for you.
6. If you choose to breast feed, we will ask you to provide small samples (10ml) of breast milk on two (2) occasions in the first 7 months.
7. You will have 4 clinic visits with your baby (at 3, 7, 13 and 24 months of age).
8. Your child will have an allergy skin test at 2 of these visits (13 and 24 months).
9. We will ask you to complete a health questionnaire at the beginning of the study, and when we review your baby at 7 months, 13 months and 24 months of age (this will take about 15 minutes).
10. We will ask you to keep a weekly diary to note any illnesses that your child has, and to note when you introduce new foods into his/her diet.

#### *What this study entails for your baby:*

11. Taking a fish oil supplement or placebo once a day until 6 months of age (as stated in point 5 above).
12. We will collect 3 saliva samples (3 months, 7 months, 13 months). Only 0.5-1ml of saliva is needed and this is collected using gentle suction. This can produce minor discomfort for some children, but is not generally painful and does not have any lasting effects.
13. We will collect 3 urine samples (3 months, 7 months, 13 months).
14. We will do a blood test (5-10ml of blood only) at 7 months, 13 months. We will use Emla (anaesthetic) cream to reduce any discomfort this may cause.

This will not interfere with your child’s normal care in any way. You may withdraw from the study at any time. All information is recorded confidentially. **Please contact A/Prof Susan Prescott if you have ANY concerns, on Ph: 0409 441 964. If you have any complaints regarding the conduct of this study please contact the Director of Clinical Services on 9340 2222**

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# Childhood Allergy and Immunology Research

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