

Baby Biotics Frequently Asked Questions



1. What are probiotics?

Probiotics are healthy bugs, or good bacteria, that are believed to be good for your health. They are in some yoghurts, infant formulae and foods. There are many different kinds of probiotics.

2. What is *Lactobacillus reuteri*?

Lactobacillus reuteri is one type of probiotic that has been shown to be naturally present in a baby's tummy and in mothers' breast milk. *Lactobacillus reuteri* is the probiotic used in this study.

3. Which drops will my baby be taking?

Your baby will be taking either the probiotic drops or the placebo drops (that is, the drops without the probiotic). There is a 50% chance of taking one or the other. It is necessary for half of the babies in the study to take the placebo drops to find out whether the probiotic really works.

4. Can I find out whether my baby gets the probiotic or the placebo?

Unfortunately, you cannot find out whether your baby gets the probiotic or the placebo during the study. The researchers also don't know which drops your baby is getting. This is to ensure the results of the study are not biased. It is possible to find out which drops your baby has been taking at the end of the whole study and after the results have been analysed, likely in 2013.

5. What is in the drops?

The placebo drops contain sunflower oil and a very tiny amount of maltodextrose (a simple form of sugar). The probiotic drops contain *Lactobacillus reuteri* and sunflower oil.

6. What do the drops taste like?

The drops are tasteless. You cannot taste any difference between the probiotic and placebo drops.

7. My baby is taking an anti-reflux medication (Zantac / Losec) and has been diagnosed with reflux. Can my baby still participate?

Yes, your baby can still participate in the study even if he/she is on anti-reflux medication. In fact, many of the babies in our study have been diagnosed with reflux or are on anti-reflux medications.

8. Do the drops have side effects?

There have been no reported side effects of using *Lactobacillus reuteri* in normal babies. *Lactobacillus reuteri* has been studied in more than 5000 individuals of all ages. They have been used in premature as well as term babies.

9. Can the drops be taken with other medications?

Yes, the drops can be taken with other medications. There are no known interactions with other medications.

10. Can the drops make my baby's crying worse?

There have not been reports of the drops making babies' crying worse. On the contrary, there have been studies showing the drops reduce some babies' crying. If you feel that the drops might be making your baby's crying worse, try to give the drops at a different time of the day, and see whether it makes a difference. If you are unsure, please call Dr Valerie Sung on 0439 290 580 and she can discuss with you what to do. IF POSSIBLE, PLEASE DO NOT STOP THE DROPS WITHOUT CONTACTING DR SUNG FIRST.

11. What do I have to do before the first visit?

Before the first visit, it would be great if you could collect a poo sample from your baby and store it straight into your freezer at home. If you have been given or sent a study pack, you may be able to fill out a questionnaire as well. This questionnaire takes about 10 minutes to complete.

12. How do I collect a poo sample and what do I do with it?

If you have been given or sent a specimen jar, you can scoop some poo from your baby's nappy and put it in the jar, then straight into the freezer. If you haven't been given or sent a specimen jar, you can wrap one/some of your baby's dirty (poo) nappies in a plastic bag, and put it straight into the freezer. We need about a teaspoon to a tablespoon of poo. You may need to collect poo from a few nappies to get enough. We will collect the frozen poo sample at the first visit. Please label or note down the date and time when you collected the poo from your baby.

13. How do I give my baby the drops?

You will give your baby 5 drops of study liquid every day. The easiest way is to drop the 5 drops onto a spoon and give it to your baby that way. The drops can be given with or without a feed. We recommend you choose the morning feed to give your baby the drops, so that you can remember to do so every day.

14. What if I forget to give my baby the drops?

If you forget to give your baby the drops, give the drops to your baby as soon as you remember to, at any time of the day. You cannot "overdose" your baby with the drops. If you have missed giving your baby the drops for a day or more, you can tell us by filling in the weekly questions in the diary.

15. What if I want to stop giving my baby the drops?

If you want to stop giving your baby the drops, please call Dr Valerie Sung on 0439 290 580 so that she can discuss this with you. IF POSSIBLE, PLEASE DO NOT STOP THE DROPS WITHOUT CONTACTING DR SUNG FIRST.

16. What if I forget to fill in the diary?

If you forget to fill in the diary, just fill it in as soon as you remember, for example the following day.

17. What happens at the end of the study?

At the end of the study, please collect another poo sample from your baby's nappy, put it in the specimen jar provided, label it with the date and time of collection, and put it straight into the freezer. Please also fill out the 1 month questionnaire if you can; it takes less than 5 minutes to complete. One of the study researchers will contact you to make a time to collect the following:

- a) the study diary
- b) the 1 month questionnaire
- c) the study bottle (please don't throw the bottle away!)
- d) the poo sample

18. Can I get the probiotic drops after my baby completes the study?

Unfortunately, you cannot get the probiotic drops after your baby completes the study. You cannot buy the *Lactobacillus reuteri* probiotic drops in Australia. However, we hope that by the time your baby completes the study, he/she will be more settled, as colic usually naturally gets better as your baby grows older.

19. How do I find out more about the study?

You can find out more about the study by:

- a) Calling Dr Valerie Sung on 0439 290 580 / 9345 4363
- b) Emailing one of the study researchers on baby.biotics@rch.org.au
- c) Visiting our website at www.rch.org.au/ccch/babybiotics