

# WHAT IS GASTRO?



Gastroenteritis (gastro) is an infection of the gut that can make children feel sick, weak and not want to eat or drink. The infection causes fever, vomiting and lots of runny watery poo. Children with gastro can become very sick, especially younger children, and may need to go to hospital to get extra fluids. These fluids can be given through a tube that goes in their nose and down to the tummy or through a vein in their arm, until the child is well enough to eat and drink for themselves.

In the Northern Territory the most common cause of Gastro is a virus called rotavirus. Children in the NT are given an oral vaccine called Rotarix at 2 and 4 months of age, to help protect them against rotavirus infection. Even though we have this Rotarix vaccine, Aboriginal children are still getting sick with gastro. They are about 20 times more likely than non-Aboriginal children to go to hospital with gastro.

## What is the ORVAC study?

We want to see if giving Aboriginal children an extra dose of Rotarix vaccine between 6 months and 12 months of age will give their body extra protection against rotavirus infection and stop them getting sick with gastro in the first 3 years of life.

*We are hoping that this will mean less hospital visits with gastro for young Aboriginal children.*

For more information, or in case of a reaction that you are concerned about please contact:

### Study Team

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If you have concerns or complaints about your rights or the conduct of this study, please contact:

The Human Research Ethics Committee of the NT  
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*discovery for a healthy tomorrow*

## ORVAC Study Healthy Tummies for Kids



*What can we do to reduce the number of hospital admission for Aboriginal children because of GASTRO?*

**Participant Information Sheet**  
This is for you to keep

## Can I join the ORVAC study?

Your child can be in the ORVAC study if:

- Your child is between 6 and 12 months of age and they live in the Northern Territory
- They have received at least one dose of the Rotarix vaccine (we can check this for you if you aren't sure)
- You consent for your child to be part of the study

**You do not have to say “Yes”.**

**You can change your mind at any time.**

**If you say “No” this will not affect you or your child's care.**

## What does the study involve?

If you agree to join, we will:

- Get you to sign a consent form to say you are happy to be involved in the study. You can choose to pull out at any time.
- Check the Australian Childhood Immunisation Register to see if your child has had one or two doses of Rotarix vaccine before.
- Randomise (like flipping a coin) your child to either receive the vaccine or the placebo (inactive medicine). No one involved in the study will know which one your child receives until the end of the study.
- Call or send you a text message or contact you on social media 14 days after the extra dose of Rotarix vaccine to see if you have any concerns about your child or questions about the study.

## DID YOU KNOW

Up to 77% of Aboriginal babies in the Northern Territory will have an episode of diarrhoea by their first birthday.



## What does the study involve (continued)...

If you agree to join, we will:

- Check your child's health records (clinic records and hospital records) up until their 3<sup>rd</sup> birthday, to see how many times they get sick with gastro.
- Your privacy will be protected and your name will not be included in any information published about the study. Only the researchers will know your name. The information we collect will be stored for up to 25 years.

## What does the study involve (continued)...

### Optional

- If you agree we may contact you to remind you about other routine immunisations up until your baby is 6 months old
- We can check the Australian Immunisation Register to see if your child is due any other vaccines and can help you make an appointment at your local clinic.
- At the end of the study we can record that your child was given an extra dose of Rotarix vaccine in the NT Immunisation Register.

## Benefits and Risks

The study medicine may help protect your child from Rotavirus infection. There is a small risk that your child may have some side effects, including a special type of gut blockage where one part of the intestine folds inside itself (this is called intussusception). If you have any questions about any side effects, please ask your doctor or one of the research staff.

The research may not directly help you or your child, although the research could help your community, your friends and family in the future.