

What are the risks and benefits?

Risks

- There may be no direct benefits from the study

Benefits

- Giving probiotics can help grow or maintain the living good bacteria in your baby's tummy
- Probiotics could protect your baby from infections
- Probiotics help to develop your baby's immunity
- The research will help us understand more about the benefits of giving probiotics to babies
- This study may improve the future lung health care of babies in the Northern Territory
- You will receive a \$20 gift voucher, a baby singlet, baby bib, waterbottle, carry bag and certificate of participation for your baby as a thank you at different study timepoints

Did you know

Most adults with sick lungs had lots of chest infections when they were babies.

Contact Details

If you are unsure, have any questions or want more information about the study, please contact:

Dr Tejal Shah, Study Manager
Menzies School of Health Research
Ph: 0436 314 405
Email: ProKids@menzies.edu.au

Dr Michael Binks, Chief Investigator
Menzies School of Health Research
Phone: 0423 194 728
Email: michael.binks@menzies.edu.au

Dr Peter Morris, Site Investigator
Top End Health Service
Phone: 0428 910 254
Email: peter.morris@menzies.edu.au

This study is administered by Menzies School of Health Research and authorised by Northern Territory Health.

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 Department of Health & Menzies School of Health
PO Box 41096, Casuarina NT 0811
Phone: (08) 8946 8600
Email: ethics@menzies.edu.au
HREC number: 2023-4759

NT Health Research Governance Officer
Phone: 08 8922 7764
Email: nthealth.rgo@nt.gov.au
Reference number: 2024/2181



NT HEALTH

Menzies School of Health Research (HQ)
John Mathews Building (JMB), Building 58, Royal Darwin Hospital Campus, Northern Territory, Australia 0810.

Website: menzies.edu.au

Pro-Kids

Probiotics to reduce chest infections in First Nations babies



Pro-Kids

“Protecting small lungs for healthy babies”

PARTICIPANT INFORMATION SHEET

This is for you to keep.

Pro-Kids Study Participant Information and Consent Form_V1.2_14102025 for Study Protocol V1.2 Dated 14102025

Why we care about chest infections?

- Chest infections are common in Aboriginal babies
- Chest infections can make babies very sick
- Chest infections as a baby can make your lungs weak as an adult

What are probiotics, what do they

- Probiotics are 'good bacteria'
- ***Lactiplantibacillus plantarum*** is a probiotic
- It could protect your baby's tummy from germs
- It could strengthen your baby's immune system
- It could prevent chest infections in your baby
- If you join this study, your baby will receive a supplement containing ***Lactiplantibacillus plantarum*** and **fructo-oligosaccharides (sugars)**.
- We call this supplement LpFOS
- LpFOS is ingested orally in water or breast milk
- LpFOS is safe for babies

What is the Pro-Kids study



"We want to know if giving probiotics to babies can improve immunity and stop chest infections."



Lactiplantibacillus Plantarum,
the 'good bacteria'

Can my baby join the Pro-Kids study?

Yes, if you are:

- Aged 18 years or over and having a baby of Aboriginal descent
- A resident of a participating community
- Willing to provide written consent in English

What does the study involve?

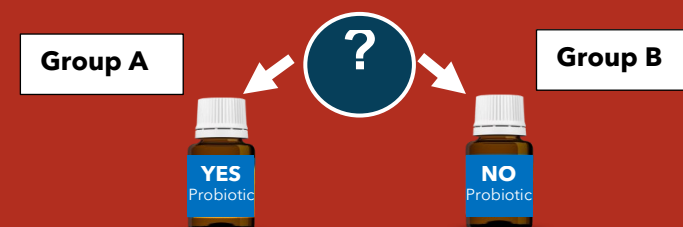
- We will visit you and your baby 5 times starting between birth and your baby's 1st birthday
- Your baby will receive:
 - **3mls** of study medicine (in water or breast milk) every day for 7 days starting within 3 days of birth
 - **Probiotics OR Placebo** (No probiotics) (you will not know which one)

We will also collect:

- Information from your medical records to check your pregnancy health
- Cord blood (birth) after birth
- Breast milk when your baby is age 7-13 days (finished the study medicine) and at age 1 month
- Baby's blood (via venepuncture, heel or finger prick) at 1, 4 and 7 months of age
- A nose swab from your baby at day 7-13, 1, 4 and 7 months of age
- A stool (poo) sample from your baby at birth, day 7-13, 1, 4 and 7 months of age
- Information from your baby's medical records will be collected between birth and 12 months of age to check for chest infections and other health conditions

"Your information will be kept private at all times"

How will we know if probiotics work



"We will count the number of chest infections in each group"

We will use the samples to check:

- How probiotics affects your baby's immune function and capacity to fight germs
- Microbes in your baby's nose and tummy to check how well probiotics works for your baby

Before you join, you will need to sign a consent form. This means:

- You understand why we are doing the study
- You understand the risks and benefits
- You understand we will visit and contact you
- You are happy for us to collect some samples
- You are happy for us to check your medical records
- You agree to be a part of the study with your baby

You do not have to say "Yes"

**If you say "Yes" you can still change your mind
Saying "No" will not affect you/your child's care**

Optional consent (you can say no):

- Permission to use your deidentified data and samples for future respiratory health research
- Permission to contact you for any future studies
- Any future research will require new approval from the Human Research Ethics Committee

Pro-Kids Study CONSENT FORM

This form means you can say **NO**

Postal: PO 41096, Casuarina NT 0811, Australia
Location: John Mathews Building (Bldg 58), Royal Darwin Hospital Campus, Rocklands Drv, Casuarina NT 0810
Ph: (08) 8946 8600
Fax: (08) 8946 8464
Website: www.menzies.edu.au
ABN: 70 413 542 847

My name is: _____

**The Pro-Kids study has been explained to me and I know what is involved.
I have had the opportunity to ask questions about the study, I understand:**

- It is OK to say NO and that, if I say YES, I can change my mind later.
- The possible risks, side effects and benefits being involved in the study.
- That my baby and I may not directly benefit by taking part in this study.
- All information collected about my baby and I will be kept confidential.

By signing this form, I give consent for myself or my child:

"If unclear, please discuss with a team member before proceeding."

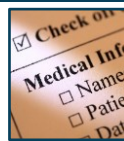


1. To give my baby a probiotic or placebo for 7 consecutive days.



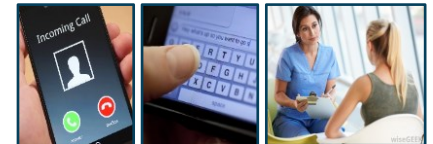
Probiotic: Lactiplantibacillus plantarum plus fructo-oligosaccharides

2. To have our medical records accessed from birth until my baby's 1st birthday.



Includes: Aboriginal medical health services, medical centers, clinics, hospitals and any other health records

3. To be contacted regularly via phone/email/social media.

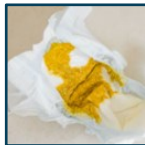


4. To have the following samples collected from me (breast milk only) and my baby over 5 study visits from birth for approximately 7 months:

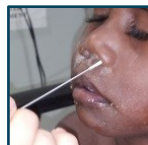
Cord blood



Baby stool (poo)



Baby nose swab



Baby blood



Mother's breast milk



Optional

I agree to have my own and/or my child's samples and information (NO identifying data) stored and used in future child respiratory health studies. You can say no and still join the study. Yes ☐ No ☐

I agree to be contacted for future clinical research studies at Menzies School of Health Research Yes ☐ No ☐

Feedback

I would like updates and a copy of the research outcomes by post / email / social media? Yes ☐ No ☐

If Yes, contact details _____

Participant / legal care-giver of participant Signature	_____ Date	Research staff Signature	_____ Date
I understand what I am signing. I will be given a copy to keep.		I have verbally explained the project to the participant. I believe the explanation was understood.	
Interpreter / witness signature (N/A if not applicable)		_____ Date	