Prophylactic Antibiotics to Prevent Chest Infections in Children with Neurological Impairment (PARROT) Study

Queensland Children's Hospital

Participant Young Person

INFORMATION SHEET

Prophylactic Antibiotics To Prevent Chest Infections In Children With Neurological Impairment

"This is for you to keep"

Queensland Children's Hospital

Participant Information Sheet

Project Title:	Prophylactic antibiotics to prevent chest infections in children with neurological impairment (**PARROT**) trial.
HREC Number:	HREC/19/QCHQ/56353
Lead Site:	University of Liverpool, United Kingdom (UK)
Australian Chief Investigator:	Prof Anne Chang
Investigator Team:	Prof Dinah Reddihough, Dr Kim McLennan, Prof Katrina Williams, Assoc/Prof Brent Masters, Dr Gabrielle McCallum, Dr Adrienne Harvey, Prof Paul McNamara
Local Contact Person:	Ms Anne Cook 07 3069 7283
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Introduction

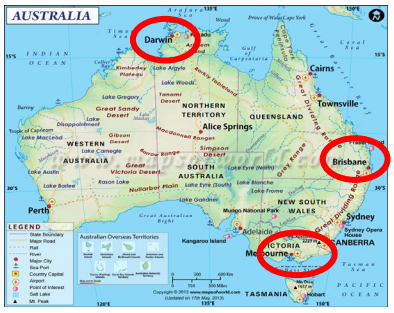
It is important for you to read this booklet so that you can understand what this research study is all about. A member of the research team will talk to you about the study and answer any questions you may have.

Taking part in this research project is **voluntary**. **This means you can say NO**. You do not have to take part, and you can withdraw from the project at any time without explanation. This will not affect your access to treatment options and care at Queensland Children's Hospital.

Once you understand what the research is and if you agree to take part in it, you will be asked to sign a consent form. Signing the consent form means that you understand what the research is about and you agree for you to take part. You will be given a copy of this information sheet and the consent form to keep for yourself.

Who is involved in the PARROT Study?

In Australia this study is funded by the National Health and Medical Research Council and is recruiting in 4 hospitals across Australia (see below).



- Royal Darwin Hospital, Darwin
- Queensland Children's Hospital, Brisbane
- Royal Children's Hospital, Melbourne
- Monash Children's Hospital, Melbourne

In the UK, this trial is funded by the National Institute for Health Research HTA Programme and approximately 40 hospitals are involved.

Why is this study important?

Non-progressive neurological impairment is caused by conditions such as cerebral palsy and leads to physical disability. Some children with neurological impairment are at high risk of lower respiratory tract

infections, which often lead to repeated hospitalisations. This places a huge burden on children, their families and healthcare services. To prevent lower respiratory tract infections, some children and young people are prescribed long-term preventative antibiotics. This practice varies among doctors and is currently based on very limited evidence. It is important to find out whether treatment with long-term antibiotics

- Does help prevent recurrent lower respiratory tract infections
- Improves quality of life
- Has any impact on types of bacteria and viruses in the respiratory tract
- Is safe and cost effective
- Impacts the viruses and bacteria in the respiratory tract eg. does it make them antibiotic resistant

What are the aims of the PARROT study?

We want to find out if giving 12 months of 3 doses per week of azithromycin (an antibiotic) reduces the number of hospitalisations for lung infections over a 12-month period (compared to when a placebo or pretend medication is given).

We will also look at the effect of 12-months of treatment on:

a) Parent reported health-related Quality of Life (QoL) for parent and child/young person
b) The child/young person's nutritional status
c) The amount and quality of sleep for the parent and child/young person
d) The child/young person's Liverpool Respiratory Symptom Questionnaire-Neuro score
e) Cost-effectiveness of resources used/costs associated with the trial medication
f) Nasal bacterial and viral carriage and antibiotic resistance

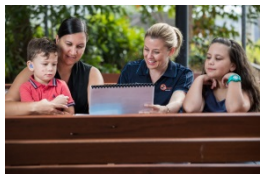
Who can be involved in the PARROT study?

Children and young person who:

- Are aged 3-17 years old
- Have a diagnosis of non-progressive, non-neuromuscular neurological impairment.
- Persistent respiratory symptoms
- Received at least 2 courses of oral antibiotics for lower respiratory tract infections in the last 12 months and/or 1 hospitalisation.

What will my family and I have to do if I am part of this study?

At ENROLMENT



Consent: The parents/guardian of an eligible child/young person will be asked to give consent for their child/young person to be enrolled in the study.

Medical history/questionnaires: Parents/guardians will be asked questions about where they live, family history, their child/young person's lung health, attendance to clinics/GP/hospital for lung-related illnesses in the last 12 months, routine medications. Parents/guardians and child/young person (where appropriate) will also be asked to complete symptom/*Quality of Life*/health-related questionnaires.

Medical records/economic information/clinical:
With permission from your parent/guardian and you, we will look at your medical charts and electronic records for:

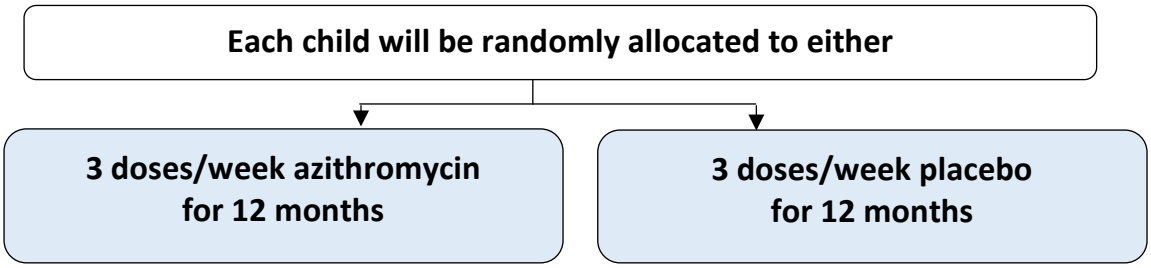
- Information on lower respiratory tract infections
- Details of clinic or hospital admissions and immunisations
- Other health related conditions which may change lung function (i.e. surgical procedures)

This information will also help work out the cost for the economic analysis

Clinical samples:

- -At enrolment you will have nose swab (or nasopharyngeal aspirate) taken to check for bacteria and viruses

Study Medication:



AFTER ENROLMENT

Study medicine: You will take study medications (either active azithromycin or placebo) 3 times per week for 12 months. The medication will be a liquid. Neither you nor the study staff at your hospital will know whether you are receiving the active azithromycin or the placebo

Adverse events: During our regular contacts with you and your parent/guardian, we will monitor any adverse events that you are experiencing after you start the study. The most common side effects (in >1% of users) of azithromycin are mild gastrointestinal symptoms such as nausea, vomiting, diarrhoea and abdominal pain. For any medication there is also a very small chance that side effects that are not yet known to be related to the study medications may occur. Please discuss with your doctor any concerns about the potential side effects of this medication.

Study plan after enrolment visit

Follow-up contact by phone or email: We will contact your parent/guardian at 1, 2, 4, 5, 7, 8, 10, 11 and 13 months to see how your lung health and general well-being are (i.e. if you have been unwell, or had any lower respiratory tract infections or had any other treatments). This will be done through phone calls or emails (whatever contact mode is best for your parent/guardian). The 13 month follow-up contact will be 1 month after completion of study medicine.

Clinic visit: You will be asked to attend the clinic at 3, 6, 9, 12 and 18 months. Parent/guardian and child/young person (where appropriate) will be asked to complete symptom/QoL/health-related questionnaires. A sleep diary will also be completed at enrolment and at 12 months.

Medical Chart/Economic review: At each contact point, we will look in your medical chart to record any community or hospital treated acute lower respiratory infections and other medical conditions. This information will also help work out costs for the economic analysis.

Specimens: With your permission, we will collect:

- A nose swab (or nasopharyngeal aspirate) at enrolment to study and then at the 6, 12 and 18 month clinic visits and during any unscheduled hospitalisations for respiratory infections
- A sputum sample (or cough swab) if you are hospitalised with a lung infection.

These will enable us to look at bacteria and viruses in the respiratory tract and their antibiotic resistance.

Unscheduled visits: If you are hospitalised with a lung infection, we will collect information about your symptoms, new medications, adverse events etc relating to that illness. With your permission, we will also collect a nasal swab and cough/sputum sample (where able).

What are the potential risks for me in this study?

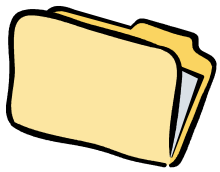
We do not expect bad side effects from the study medicine. Sometimes antibiotics can cause things such as rashes, hives, diarrhoea and nausea or other problems that have not been seen before. Some children will be in the placebo group (pretend medicine) which is not known to cause any health problems. Doing a nose swab or nasopharyngeal aspirate may cause some minor discomfort at the time for a very brief period.

What are the benefits of this study?

This study will provide evidence for or against the use of azithromycin to reduce the number of lower respiratory tract infections. The results of this study will also help work out if prophylactic antibiotics reduce health care costs, improve quality of life while not adversely impacting on the respiratory bacteria. If effective, the results of the study will inform clinical practice of doctors treating children with neurological impairment and change evidence-based guidelines nationally and internationally for this patient group.

Access to medical records

By signing the consent form, your parent/guardian is giving the study team permission to look at your medical records at the hospital, health centres, general practitioners, and the National childhood immunisation databases.



Do I have to be involved in this study?

- **No, you are free to decide whether or not you want to be part of this study**
- If you choose not to take part, you will still receive the best available treatment and care. If you decide to join the study then change your mind you can take drop out at any time and will still receive the best available treatment and care.

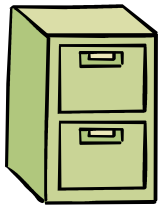
The role during the study

- Make sure you take the study medication 3 times/week for 12 months.
- Attend the clinical visits at 3, 6, 9, 12 and 18 months.
- Your parent/guardian will be required to respond to either phone or email contact by the research staff – approximately monthly
- You are free to stop taking part in the study at any time. If you decide not to continue in the study, then we ask that you let us know by either email or phone.

Our responsibilities as a researcher

- Regular follow-up to make sure you are tolerating the study medicines well.
- Agree to work within national/international guidelines for Good Clinic Practice.
- There are a number of other independent groups who will monitor the study
  - Human Research Ethics Committees
  - Independent Data Safety Monitoring Committee

What will happen to the information collected?



- The study team will share information about you with local medical staff so that they can give them the best possible treatment.
- All study information will be kept in a locked secure cabinet/location for 25 years.
- The de-identified information collected from all Australian participants will be sent to the UK to be merged to the information from UK participants. By doing this there will be enough participants to answer the aims of the study. The UK study team initiated this study internationally but will not be provided with any information to identify you.
- The results will be published in journals and talked about at meetings and conferences (no names or details will be made public).
- With your parent/guardian's written permission (consent form), your de-identified data will be used for future research relating to this study or for other research that will be valuable to lung health.

What will happen with the specimens?

- Sputum, nasopharyngeal aspirate, nasal and cough swab samples will be stored at our research laboratories and then split (if there is enough sample) and de-identified portions sent to Menzies School of Health Research, Darwin and University of Liverpool Biobank, UK
- At the end of the study, it is your choice what you want to do with the specimen. You can choose to have the specimens kept in the freezer or destroyed at the end of the study.

Ethical Approval

We have full approval from the Human Research Ethics Committee to conduct this study (HREC/19/QCHQ/56353). We will provide regular reports to update them on how the study is going.

Contact Details

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Complaints and concerns may be directed to the Human Research Ethics Committee
Children's Health Queensland Human Research Ethics Co-Ordinator
Ph: (07) 3069 7002; Email: CHQEthics@health.qld.gov.au OR
Children's Health Queensland Research Governance Office
Ph: (07) 3069 7008; Email: CHQ_RGO@health.qld.gov.au

Thank you for reading this information sheet.