SPECIAL STUDY!

Why are we doing this study?

- Increasing evidence shows that the majority of children labelled as antibiotic-allergic, may actually not be allergic to the antibiotic at all.
- Rashes frequently observed in children receiving antibiotic treatment are often due to the underlying illness and are not an indication of an antibiotic allergy.
- Adverse consequences for patients who are falsely labelled as "antibiotic allergic", is that they may be treated with antibiotics that may be less optimal than the antibiotics that the "allergic" label has ruled out.
- Alternative antibiotics may not be always available overseas.
- Adequate testing strategies for antibiotic allergies are urgently required in order to provide the best clinical care to your child- for now and for the future

What is the aim of the study?

This study will accurately

- Define the true rate of antibiotic allergies in Western Australian children.
- Safely guide recommendations on future management of children with an antibiotic allergy in Australia.

Is your child eligible to take part in the Study?

To be eligible for the study your child needs to be between six months and 16 years of age and have a reported allergy to a specific antibiotic.

What is the process if your child takes part in the Study?

You will be contacted by a member of the research team who will ask you some background questions relating to your child's allergy. You will then be given a telephone consult with a medical doctor. Once your child has been confirmed suitable for the study they will be randomly allocated (this is called study randomisation) into two groups. This random allocation of the groups is important because it allows for chance allocation rather than being a choice made by your doctor.

Group one will be offered testing for their antibiotic allergy through an antibiotic testing challenge within two months of enrolment. Group two will undergo current standard care. All participants will be followed up with telephone calls for two years (every three months) where you will be asked questions about all medical visits and use of antibiotics.

All participants of group two will be offered de-labelling through Perth Children's Hospital (PCH) after the two year study period.



What does the testing involve?

Depending on your child's history of antibiotic allergy, two different testing methods will be used which is dependent upon your child's allergy history.

Method one includes skin testing and potentially oral challenge. Method two includes oral challenge only. Skin testing is where a minute amount of the suspected antibiotic and other different types of antibiotic are "pricked" and then injected into the top layer of the skin on the forearm to observe for reactions. The oral drug challenge is where varying amounts of the antibiotic are administered orally in increasing concentrations to observe for reactions.

These tests occur under the supervision of trained medical staff with immediate access to facilities for handling the unlikely event of a severe allergic reaction.

After the challenge, if your child is found to be truly allergic to the culprit antibiotic then we will ask for a blood sample to be drawn.

Safely

Preventing

Errors and

Complications due to

Inappropriate

Allergy

Labelling

Safely Preventing Errors and Complications due to Inappropriate Allergy Labelling!

What will be the benefit of the study?

This study aims to benefit other people, especially children, in the future in several ways. We hope it will allow us to develop faster tests for antibiotic allergies that could be conducted at the bedside. The process of de-labelling patients as antibiotic allergic means that more appropriate antibiotics could be used for that patient in the future. The benefit of this could mean less overall development of antibiotic resistance, less cost to the healthcare system and the possibility of shorter hospital stays and fewer re-admissions due to antibiotic failure.

Who has approved and funded the study?

This study has been approved by the Child and Adolescent Health Service Ethics Committee.
The Perth Children's Hospital Foundation is kindly funding the study.

Who to contact for more information about the study:

If you would like any more information about this study, please contact the research team.

They are very happy to answer your questions.

Contact details:

M 0435 298 548 **Q** PMH.AllergyDe-labelling@health.wa.gov.au

This study is kindly funded by:



Perth Children's Hospital Foundation is the main fundraising body for PMH and Perth Children's Hospital as well as the wider Child & Adolescent Health Service in Western Australia. Formerly PMH Foundation, we have provided over \$70 million in grants to PMH to purchase state of the art equipment, fund advances in medical research, grow staff expertise, and make being in hospital less daunting for kids and their families.



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