



**We want to invite you and your child to participate in the ARROW study. This is a research study for preschool-aged children who suffer from wheezing illnesses that cause them to come to the hospital. We will test a drug called OM-85 to see if it helps keep children like yours, with wheeze, out of the hospital.**

### **About wheezing illnesses**

Children with a wheeze have tightened, narrowed airways. When children have a wheeze or whistling in the chest on breathing out, they can also have fast breathing or difficulty breathing. Often children need to use their inhaler (reliever medication) during a wheezing episode. Wheezing illnesses are the most common reason young children come to the hospital worldwide, causing a lot of stress for the children and their whānau. A viral infection causes most wheezing illnesses in preschool-aged children. Most children with wheeze grow out of it as they reach school age, while others go on to develop asthma.

### **About the study treatment**

OM-85 is a medication taken by mouth that contains small parts of killed bacteria. OM-85 helps to boost the immune system by stimulating immune cells in your tummy to fight viruses and reduce inflammation caused by viral infections in the lungs. OM-85 is used in many parts of the world, and we know it is a safe medicine for children. Some small studies have shown that it reduces wheezing illnesses in young children. We now need to confirm this in a large study and learn whether it helps to keep young children out of the hospital.



## About the ARROW Study

The ARROW study will test whether OM-85 helps prevent pre-school aged children with wheeze from coming to the hospital. We will do this by recruiting over 2000 children into this study in New Zealand and Australia. Each child will be allocated to one of two groups: a treatment group (OM-85) or a no-treatment group (placebo). Each child's group will be decided by chance, like tossing a coin, and your child has an equal chance of being in either group. OM-85 and placebo will look and taste the same, and you will not know which treatment your child is receiving until the study is completed.

## Who can be involved?

Your child can participate in this study if they:

- are aged between 1 and less than 6 years.
- had at least one hospital admission for wheeze lasting more than 6 hours.
- had two or more wheezy illnesses in the last year, lasting more than six hours, associated with fast breathing or difficulty breathing.

Whether you choose to participate in this study or not is your decision. If you decide not to participate, this will not affect your child's medical treatment or relationship with their doctors, nurses, or hospital.

## What does the study involve?

1. The research team will meet with you to discuss the study, ask for your consent, and complete a baseline survey about you and your child. The meeting can occur at the hospital or home, face-to-face, or via a video call meeting (i.e., zoom).
2. You will be posted the study medication (either OM-85 or placebo) every three months via courier. Your child takes the study medicine for the first ten days of each month for 12 months. The study medicine comes as a powder in a capsule. You can pour the powder into your child's preferred drink, e.g., water, milk, or juice.
3. We will collect information about your child's health through electronic diaries sent to you via email every seven days.

## More information

You can access the QR code for more information and a video about the study.



You can also contact the ARROW study team.

Email: [arrow@auckland.ac.nz](mailto:arrow@auckland.ac.nz)  
Phone/txt: 027 200 4680 or  
Call: 0800 CIRCAN (0800 247226)

