



THE WATCH TRIAL

Watchful waiting for Aboriginal and Torres Strait Islander Children with AOM)

Participant Information Sheet – Parent/Carer/Child

What is the study about?

Middle ear infection is a big problem for children and can cause hearing loss. One type of middle ear infection is acute otitis media (AOM). There are two main treatment options for AOM: Antibiotics or observation without antibiotics, called “watchful waiting”.

We are studying which of these treatment options is best for urban Aboriginal and Torres Strait Islander children with AOM.

Why do we need to do this study?

The current Australian guidelines say either “watchful waiting” or antibiotics are reasonable choices, but the previous guidelines recommended antibiotic treatment.

Using too many antibiotics can cause antibiotic resistance and side effects like diarrhoea. Children with AOM are usually better within a week, whether they had antibiotics or not. Those who have antibiotics have less pain but more diarrhoea and vomiting by the 3rd day.

Randomised controlled trials (RCT's) are the best way to work out the best treatment. *WATCH is an RCT which will provide the best evidence on managing AOM in your community. This information will be used in future guidelines.*

We need approximately 500 children enrolled in the study to be able to tell which treatment is best.

How will this study help me or others?

At the moment we do not know what treatment is best for urban Aboriginal and Torres Strait Islander children with AOM. *Your participation will help Aboriginal and Torres Strait Islander kids get the best and safest treatment in the future, helping doctors and parents make the best choice for treating AOM. WATCH will keep a close watch on your child during this illness and you can contact us if you have any concerns.*

For assisting with this research you will receive two \$25 supermarket vouchers - one at the beginning and another one week later. Your health service will also receive a payment when you join the study and when you complete it.

What is involved?

If you choose not to take part in WATCH, this will not have any effect on your child's treatment or on your relationship with the GP, Nurse or health service.

If you choose to take part, we will collect information about your child and your experience of the study.

We will check your child's ears. Then your child will be put into one of two groups by a special computer program – it's like tossing a coin.

In one group kids will immediately receive antibiotics. In the other group they will not receive antibiotics at this stage. Both groups will be offered pain relief. Your GP or Nurse can change treatment at any time if you, or they, feel it is necessary.

Your GP or Nurse will check your child again A WEEK after you first come in. Our Research Officer will also phone or visit you 3 days after the ear infection and again at 2 weeks, and check your child at clinic or visit you at 7 weeks. They will ask some questions and do a test or a video of your child's ear. We will also contact you to ask about what you thought about being in the study.

A GP or Nurse will also look at your child's clinical record after 3 months to check if there have been any problems. The Research Officer will also check the National Immunization Register for your child's immunisation history.

Will the study have any discomforts or risks?

We do not expect your child to experience anything more than slight discomfort from the ear examinations. The antibiotics that your child will receive if you are in the “antibiotic group” will be the usual treatment for AOM and side effects will be explained by your GP or Nurse.

We use the best instrument to check your child's ear and it can be slightly uncomfortable but should not be painful. You can see the images we take on the screen.

This study is very unlikely to result in any serious injury as it follows routine practice at all times. However, you should contact your GP or Nurse if you have any concerns. You still have the usual legal rights to compensation

THE WATCH TRIAL

Watchful waiting for Aboriginal and Torres Strait Islander Children with AOM



Can I withdraw from the study?

Participation is completely voluntary and even if you agree, you can change your mind later. Leaving the study will not affect your care in any way.

If you withdraw from the study, you can choose to have some or all of the information collected on your child, withdrawn from the study at that time.

What if I have a concern?

You can talk to your GP or Nurse, the research officer or the study leader, Professor Jenny Reath by phone: 0412 586 135; or by email: j.reath@westernsydney.edu.au.

If you would like to talk to an Aboriginal and/or Torres Strait Islander representative please contact [insert name]

If your concern is about how we are running WATCH, you can contact any one of the human research ethics committees listed below.

How will the information I give be used?

All information will be kept confidential. Information from WATCH will be used in publications and at conferences, but your and your child's name will not be mentioned. We will use a code to track all your information. The code will be stored securely under lock and key and on password protected computers.

Only qualified members of the WATCH Trial researchers will have access to your child's research records. However, representatives of regulatory authorities, including trial auditors and ethics committees can ask to access these if they decide to check the study is being run according to Australian regulations.

Who is conducting the research?

The research is being conducted by a team of people from all around Australia. It is led by Professor Jenny Reath from Western Sydney University. The people working at (insert name of AMS) Health Service are: (PHOTOS to be inserted)



D Research Officer

Has the study been approved?

This study has been approved by the following Human Research Ethics Committees:

Name	Approval number	Contact details
Western Sydney University Human Research Ethics Committee	H10369	Ethics Officer: 02 4736 0229
Aboriginal Health & Medical Research Council Ethics Committee	938/13	Secretariat: 02 9212 4777
Metro South Health Service District Human Research Ethics Committee	HREC/13/QPAH/366	HREC Coordinator: 07 3443 8047
University of Queensland Medical Research Ethics Committee	2013001093	Ethics Coordinator: 07 3365 4584
Human Research Ethics Committee of the NT Dept. of Health & Menzies School of Health Research	HOMER 13/2074	Ethics Admin. Officer: 08 8946 8600