

WHAT IS THE STUDY ABOUT?

Acute ear infections (otitis media) are one of the most common childhood illnesses.

Almost all children suffer at least one episode before the age of three years. One in six children will suffer from recurrent ear infections, which may result in hearing problems as well as affect their speech development and behaviour.

There is increasing concern about children developing a resistance to antibiotics as well as the cost of surgery for grommet insertion for these children.

Both viruses and bacteria (different types of germs) can cause ear infections. The most common germ to cause ear infections in young children is the pneumococcal germ, of which there are several types.

The pneumococcal vaccine (Prevenar) has been developed to protect against the seven most common types and has been found to be safe and effective in producing a protective immune response in babies. It is not yet known if the vaccine will be effective in reducing ear infections in children who are already known to suffer from recurrent ear infections.

HOW DO I FIND OUT MORE?

Contact our research nurses on

9340 8542

or

vtg@ichr.uwa.edu.au

In Perth, this study is run by the research nurses and doctors at the Vaccine Trials Group, Telethon Institute for Child Health Research, in conjunction with Princess Margaret Hospital for Children and the University of Western Australia School of Paediatrics and Child Health



PCV study brochure - 10/01/2005 version 3



Pneumococcal vaccine in children with recurrent

EAR INFECTIONS



WHAT ARE THE AIMS OF THIS STUDY?

The study aims to:

- reduce the number of ear infections in children
- compare the immune response in children aged 12-24 months who have recurrent ear infections, to children who do not have ear infections, when they are given two doses of the pneumococcal vaccine (Prevenar).

WHO IS NEEDED FOR THE STUDY?

Your child is eligible if he/she:

- is aged between 12 –24 months
and
- has not had the pneumococcal vaccine (Prevenar)
and
- has recurrent ear infections (three or more in the last 6 months or four or more in the last 12 months)
or
- has had no more than one ear infection

There are no placebos involved in this study.

ARE THERE ANY COSTS TO ME?

No, there are no costs involved for you or your child. Free parking is available.

HOW IS THE VACCINE GIVEN?

All of the study vaccines are given by injection into the right arm.

WHAT IS INVOLVED IN TAKING PART IN THIS STUDY?

- Five visits over a total of 12 months
- An examination by a doctor at the first and last visit and at any other visit required
- A nose swab, saliva sample and blood test at four of the visits. The blood test is made more comfortable with the use of local anaesthetic cream to numb the skin
- A painless test for glue ear
- Parents will be asked to keep a diary card of their child's temperature for one week after the vaccination, the number of ear infections and any specific symptoms their child may have during the study

