

THE RUNNY EAR STUDY (REST)

the runny ear study

PARENT SUMMARY INFORMATION

DO YOU THINK YOUR CHILD MIGHT HAVE AN EAR INFECTION WITH EAR DISCHARGE?

Aged 12 months to 16 years?

If yes, you may be able to help with The Runny Ear Study

WHAT IS THIS STUDY ABOUT?

This study is looking at the best way to treat children with a middle ear infection when there is discharge (fluid) visible coming out of the ear after the ear drum has ruptured (medical term: 'acute otitis media with discharge' or 'AOMd').

WHAT WOULD I HAVE TO DO IF MY CHILD AND I TAKE PART?

- Answer some questions about your child's illness and general health when you see the doctor or nurse.
- If your child is given antibiotic ear drops, be willing to use them straightaway and continue using for 7 days (the purpose of the study is to see if they help to ease the ear discharge and pain).
- Fill in a daily questionnaire (about 5-10 minutes each day) today and for the next 13 days about your child's recovery, either online or on paper.
- Take part in up to five telephone calls (5-10 minutes each) with a researcher, starting today, with the other four calls over the next 13 days.
- Collect a stool sample from your child on day 14 (a collection kit with instructions will be given to you) and post it to the research team.
- Fill in a questionnaire 3 months later about your child's general health, and collect and post a second stool sample.
- Possibly take part in a longer telephone interview (not all parents will be invited to be interviewed).

WHAT ARE THE BENEFITS FOR MY CHILD AND ME?

- If your child is given ear drops, they might help ease your child's ear discharge.
- You will be helping to find out whether the ear drops, would be a good future treatment for children with ear discharge and pain.
- We will send you High Street shopping vouchers at the end of the study to thank you for your time.
- Children aged 10-16 will be given a £10 voucher for taking part.
- Children under 10 will be given a piggy bank for taking part.
- An additional voucher will be sent to parents who take part in a longer interview.

IS THERE ANYTHING ELSE I SHOULD KNOW?

- **Taking part in the study will not change the normal treatment or care that your child would be given by the doctor or nurse.**
- There are three different medicine groups, one of which your child will be allocated to and be given a prescription for:-
 - 1) Antibiotic ear drops
 - 2) An antibiotic (called a "just in case" or "delayed" prescription) to be given by mouth if the ear discharge does not clear up after three days.
 - 3) Your GP's usual care, which will include an antibiotic prescription, which can be given by mouth to your child straightaway.

All children in the study will continue to receive regular care from their GP, regardless of which medicine group they are allocated to.

- The ear drops are routinely prescribed as eye drops in the UK and used as ear drops for other types of ear infection for example, infections of the outer ear.
- The ear drops are known to be safe for children. There are no common side-effects. Side-effects are extremely rare but could indicate an allergic reaction and should be reported to your doctor.
- We will give you prepaid envelopes to post the paper symptom diary and 3-month questionnaire; plus, a second stool sample kit will be sent out to you at 3 months.

Interested? Speak to the doctor or nurse today.



IRAS ID: 229293



The Runny Ear Study is funded by the National Institute for Health Research's HTA Programme HTA 16/85/01