

The OTTER Study

NOTTINGHAM
CLINICAL
TRIALS
UNIT
at the University of Nottingham

NHS
University Hospital
Southampton
NHS Foundation Trust



Omeprazole for Treatment of Term and preterm infants with gastro-oesophageal Reflux

NIHR | National Institute for Health and Care Research

Who are we approaching for the study?

We are reaching out to families with babies who are experiencing reflux despite initial treatment, and are in need of medication.



What is the OTTER study?

The OTTER study is trying to find out if a medicine called omeprazole can help babies who have reflux. Reflux happens when milk and acid from the baby's stomach come back up after feeding, instead of going down through their body to be digested. This can make some babies uncomfortable or upset. Sometimes babies are prescribed medicine called omeprazole to help with reflux, this works by lowering the amount of acid in the baby's stomach. But we don't know for sure if it really helps or if it might even cause problems. That's what the OTTER study is trying to find out. The OTTER study is comparing omeprazole with a 'placebo'. The placebo is a liquid that looks and



tastes the same as omeprazole but does not contain any of the active medicine. This comparison between omeprazole or the placebo will help us to find out if omeprazole is effective.

What are the potential benefits of taking part

Taking part in the study may not directly benefit you and your baby, but the information we collect may help us to treat baby's with reflux in the future. In addition, you will also receive a £20 shopping voucher as a thank you for taking part.



What is involved

- If you choose for your baby to take part you will be asked to sign a consent form and provide some information about yourself and your baby. Your baby will be prescribed either omeprazole or the placebo to take everyday for 4 weeks.
- After two weeks, a member of the research team will contact you by telephone to see how your baby is doing, to support you and talk through any concerns you might have.
- At regular intervals up to 6 months after your baby has been enrolled, we will get in touch by text or email to find out if you have accessed any other healthcare services for your baby.
- After six months in total, yours and your baby's involvement in the study will end.



In this research study we will use information from you, your GP and your healthcare team. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study. Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules. At the end of the study we will save some of the data so we can check the results. We will make sure no-one can work out who you are from the reports we write. The information pack tells you more about this.