

Parent Information Leaflet

MAGPIE study – Mechanisms Affecting the Gut of Preterm Infants in Enteral feeding studies

Chief Investigator: Dr Nicholas D Embleton

We appreciate that this may be a difficult time for you and would like to thank you for joining the ELFIN study. The ELFIN (Enteral Lactoferrin in Neonates) study examines whether adding lactoferrin (a milk protein) to milk feeds has any effect on infections or gut problems in premature babies. We would like to tell you about another study (MAGPIE) that we are doing alongside the ELFIN study in this hospital. The MAGPIE study simply involves collecting a daily stool and urine sample.

What is the purpose of this study?

The ELFIN study will tell us whether lactoferrin is a useful treatment for preterm babies. If lactoferrin is useful it might work in different ways. For example, it might work by increasing the numbers of 'healthy bacteria' or by affecting how the immune system works. The MAGPIE study aims to find out how lactoferrin might work. There will be about 2200 babies joining the ELFIN study, but only 480 will join 'MAGPIE'.

What will happen if my baby takes part?

The nurse looking after your baby will collect a sample of stool ('poo') from the nappy, using a sterile plastic spoon to put into a pot, and urine (using a cotton wool ball which we squeeze out) from your baby's nappy each day. The samples are stored in small pots in a freezer before they are tested. Because there is no risk to taking part we have been given permission by the ethics committee to collect samples before you decide whether you would like to take part. This is because stool and urine samples passed in the first few days can be important. If this has happened the samples will still be in your local hospital freezer. If you choose not to take part we will destroy the samples and not analyse them.

Does my baby have to take part?

No, it is entirely up to you. We are only inviting parents of babies who have joined ELFIN to be part of this MAGPIE study. You do not need to join the MAGPIE study if you do not want. A doctor or nurse will explain more to you about the study. If you choose not to take part in MAGPIE it will not affect your baby's care in any way, and it will not affect the ELFIN study. If you join MAGPIE, you can decide to stop taking part at any time.

Is there any risk or benefit to taking part?

There is no risk to taking part. Collecting the samples does not disturb or harm your baby and does not interfere with their routine medical or nursing care. The samples will not be analysed for several months or years. The tests will not benefit your baby. If the doctors on your neonatal unit need stool or urine samples as part of normal medical care they can still do this.

Will my taking part in this study be kept confidential?

Your GP will be told your baby took part in this study. We will collect personal information about you and your baby. The ELFIN research team will share the information they collect for the ELFIN study with the MAGPIE team. The NHS hospitals and regulatory authorities may carry out checks to make sure the study is performed correctly. They may see the data and check your baby's medical records as well.

What will happen to the samples?

The samples will be stored in a freezer at your baby's hospital for a few weeks before they are transported to a university laboratory in Newcastle upon Tyne, UK. Some samples will be sent to a university laboratory in Liverpool to look at body chemistry. The samples will have a barcode number (anonymised). This means that no one in the university will know the name of the baby. Only the members of the research team will know the code numbers for each baby.

What sorts of tests will be performed?

The human gut contains millions of bacteria. Many of these are 'healthy bacteria'. We want to examine this in preterm babies, and see how lactoferrin affects which types are present. Some bacteria produce chemicals (metabolites). We can detect these in stool and urine by a test called Mass Spectrometry. We want to see if the pattern of chemicals matches changes in bacteria. In the future, we think the pattern of chemicals may tell us which babies are healthy and which are at risk of developing problems. We may also do tests to see if there is any inflammation in the gut. This may help us develop newer treatments or tests in the future.

What happens if my baby needs an operation?

Unfortunately a very small number of babies become poorly and require an operation on their gut. This happens in less than 5 babies out of every hundred (<5%). If this happens small samples of the gut may be looked at in the local hospital laboratory (pathology department). If this happens we would like your permission to do a more detailed examination. We will only do this after all routine medical (pathology) tests are complete. No extra tissue specimens will be taken from your baby. The hospital will take very thin slices of the gut tissue and send to the laboratory in Newcastle, where it will be stained and examined under a microscope. This may tell us things like whether genes associated with inflammation are present, or what type of white cells (inflammatory cells) are in the tissue. This will help us better understand any diseases.

What happens to the samples after the testing is complete?

It will take several months and years to test the stool and urine samples we collect in the MAGPIE study, and we may not analyse all of them. This means we may have some samples remaining at the end of the study. We will ask your permission to store these samples longer term (for an indefinite period) in a biobank. These samples are a precious resource and can be used in further research into gut problems or infections in babies. The research may look at how their genes are working in the gut (DNA from gut cells present in the stool). Research teams may work with commercial partners to develop new techniques or tests, and some research may take place abroad. If you do not want to make these samples available for future research after the study has finished we will destroy them. The biological samples will be stored securely in a Research Tissue Bank, that has received Ethical approval and in accordance with the Human Tissue Act and national and local NHS Research Governance guidelines.

What will happen to the results of the research study?

At the end of the study we will publish the results in a medical journal, and make a summary available to parents as part of the ELFIN study. You and your baby will not be identified in any report or publication. We may want to conduct further follow up studies (for example in later childhood) as part of the ELFIN study or a separate MAGPIE study. If we do this, we will contact you through the Health and Social Care Information Centre.

Who is organising and funding the research?

The study is being run by Newcastle Hospitals NHS Foundation Trust in conjunction with the National Perinatal Epidemiology Unit (Oxford University), who are organising the ELFIN study. The study is funded by the Efficacy and Mechanistic Evaluation (EME) programme within the National Institute for Health Research (NIHR).

Who has reviewed the study?

The study was reviewed and approved by the XXX Research Ethics Committee.

What if there is a problem with the study or I wish to make a complaint?

There are no risks to your baby taking part with the MAGPIE study, but if you believe your baby may have been harmed as a result of this study due to treatment or negligence then the NHS indemnity arrangements will apply. If you think your baby has been harmed due to the research you may also have grounds for legal action or seek compensation through the research sponsor, the Newcastle Hospitals NHS Foundation Trust. You can also contact PALS (Patient Advice and Liaison Service) on the following telephone number **XXX XXXX**.

Further information

If at any stage you have concerns about this study, or the way it is being carried out, you should contact the Principal Investigator or Neonatal Nurse (their names and contact details are below). Information is also available following the links on the study website www.npeu.ox.ac.uk/elfin. If you would like to contact an independent organisation about research in babies in general we suggest you contact Bliss, the special care baby charity (www.bliss.org.uk free phone family support helpline 0500618 040)

Thank you for reading this information leaflet. Please discuss this study with the doctor or nurse who is looking after your baby, or ask to speak to a member of the neonatal research team.

Local Contact

Principal Investigator	Name.	Tel. number	xxx xxxx
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Study Sponsor Contact Details

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