PART 1

What is Research?
Research is the way we try to find answers to questions.

Why are we doing this research?
We want to find out how babies with meningitis are currently managed. Ultimately, we are hoping to find ways of improving their management and will do this by comparing their management now with what is considered to be the best management. We can then consider strategies for ensuring that management is better for all babies in the future.
We also hope to assess the development of babies when they are 2 years of age because there have been no recent studies looking at this. This will help us to understand how big the problem of meningitis in this age group really is.

Why has my baby been chosen and does my baby have to take part?
We would like to enrol babies 0-90 days of age who have had meningitis recently. Your participation is entirely voluntary and if you decide to enrol your child you would be asked to sign a consent form and given a copy to keep. If you decide not to take part, please note that this does not in any way affect the care of your baby and you can change your mind at any time without giving reasons.

What happens if my baby takes part?
You will be required to sign a consent form for your baby to take part. After getting your consent we would then contact your local Paediatrician and arrange for the Research Fellow to go to your local hospital and find out things about your baby by reviewing the medical notes. These include your baby’s presenting symptoms and signs, management in hospital including use of antibiotics and fluids and whether other kinds of medication were used.
We would also ask you to complete a questionnaire about the events leading up to the illness through to the hospital admission.
The questionnaire will ask some questions about the family as well. Although there are 14 pages, they require very short answers and tick boxes which would take you about 20-30 minutes to complete.
We do not need to see you or your baby unless you ask that we see you to help you complete the questionnaire.
However, with your consent, we would arrange for your child to have an assessment of their development when they reach 2 years of age. Please note that there is no blood test involved in this study.

**Are there any possible risks for me as a parent allowing my baby to take part?**
As we will be asking you for a detailed account of the events leading up to the illness, diagnosis and treatment, it is possible that you may get distressed by remembering all that happened. If you would like further support we enclose the details of parent support groups that you may wish to contact.

**Are there any risks to my baby for participating?**
No.

**What are the potential benefits of taking part?**
Your participation will help us to understand how bacterial meningitis cases are being managed and identify any opportunities for improvements in diagnosis and management.
Therefore, the result we get from this study may help us in the future to improve the treatment of babies with bacterial meningitis in their first 90 days of life. There is no direct benefit to you or your baby.

**What if there is a problem?**
Any complaint about the way you have been dealt with during the study will be addressed. The detailed information on this is given in part 2.

**Would my baby’s participation in the research be kept confidential?**
Yes, all the information about your participation in this study will be kept confidential. The details are in part 2.

This completes Part 1.
If the information in Part 1 has interested you and you are considering participation, please read the additional information in part 2 before making any decision.

**PART 2**
**What will happen if I don’t want to carry on with the study?**
You can withdraw from the study at any time without giving any reasons. However, the information that we have collected may still be used.

**What if there is a problem?**
If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions (contact details in the further information section). If you remain unhappy and wish to complain formally you can do this through the NHS Complaints Procedure. Details can be obtained from your local hospital.
Would my baby’s participation in the research be kept confidential?
Under the data protection laws, you have a right to know how your baby’s personal data from this study will be used so that you understand exactly what information will be collected and who will have access to it. All information which is collected about your baby will be kept strictly confidential. Any details will be anonymised so that it will not be possible to identify you or your child in our results or reports.

Will my GP be informed of my baby’s participation in the study?
We will only inform your GP if you sign the consent form allowing us to inform your baby’s GP.

Will there be any blood test involved?
No

What would happen to the results of the research study?
We plan to publish the results in a peer reviewed medical journal so that other doctors can learn about the findings of the study. We will also present the results of the study in meetings but your baby will not be identified by name. We will put a summary of the results on the website. We can let you know the results via parent support charities bulletins/websites.

Who has reviewed this study?
All research in the NHS is looked at by an independent group of people called a Research Ethics Committee to protect your safety, wellbeing and dignity. This study has been reviewed and given a favourable opinion by Cambridgeshire 2 Research Ethics Committee (Ref: 10/H0308/64).

Who is organising and funding the research?
The study is funded by the Meningitis Research Foundation (MRF) and sponsored by St. George’s, University of London.

What do I do now?
Thank you for thinking about taking part in this research. If you agree to your baby being enrolled, firstly, we would ask that you complete and return the enclosed 2 consent forms together with the parents’ return slip in a reply paid envelope provided.

On the consent form you have the opportunity to consent to any or all 4 aspects of the study:
- for us to obtain information from your baby’s hospital notes.
- for you to complete a questionnaire about your baby before their illness.
- for us to contact you again to arrange a 2 year follow up for your child.
- for us to inform your GP about your baby’s participation.

Secondly, complete the study parental questionnaire and send to us in separate reply paid A4 envelope provided.
We do hope that you will agree to take part.
For further information.
If you have any questions, you can ask your Paediatrician or
Contact the following as below:
  • Research Fellow Dr. Ifeanyichukwu Okike on 020 87252788
    E-mail: meningitis@sgul.ac.uk Website: www.neonin.com
OR
  • Chief Investigator Dr Paul T Heath on 020 8725980

For information about the study you can also contact:
  • Meningitis Research Foundation on a free phone 24 hour helpline
    08088003344.

If filling in the parental questionnaire enclosed has caused you any upset or
raised any unanswered questions, there are a number of support organisations
that you may wish to contact; alternatively you can contact the researcher as
well.

  • Meningitis Research Foundation on a free phone 24 hour helpline
    08088003344
  • Meningitis Trust on 08000281828,
  • Meningitis UK on 0117 373 73 73 and
  • Group B Strep Support on 01444416176.