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Nottingham University Hospitals NHS
NHS Trust

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**Patient Information Sheet**

**A trial of probiotics on the incidence of spontaneous bacterial peritonitis (*tummy fluid infection*) in patients with cirrhosis and ascites**

You are being invited to take part in a research study. Before you decide it is important for you to understand what it is about and what it will involve. Please read this sheet carefully and discuss it with friends, relatives or your GP if you want to. You can ask any questions about bits that you don't understand.

**What is the purpose of this study?**
Cirrhosis (scarring) of the liver can lead to tummy swelling from fluid. This fluid can become infected, and may be serious (even fatal) in some patients.

We would like to invite you to help us test a new way of stopping infection in this fluid, by using "probiotics".

When people take probiotics ("good" or "healthy" bugs) less harmful bugs are inside them. This may stop infection in the surrounding fluid.

We want to test whether these probiotics work as well as antibiotics. If they do, they may be safer to use than antibiotics.

**Why have I been chosen?**
You are being invited to take part because you have liver scarring and tummy fluid.

**Do I have to take part?**
No, taking part is up to you. If you do decide to take part we will ask you to sign a consent form and give you a copy of this information sheet to keep.

If you decide to take part you can withdraw at any time.

If you decide not to take part you do not have to give a reason, nobody will be upset and the care we still give to you will not be affected.

**What will I be asked to do if I take part?**
To begin with, we will check you over carefully to make sure it is safe for you to take part in this study. This will include blood pressure tests and a heart trace.

Samples of your blood, tummy fluid, faeces and urine will be taken. Your doctor may also have planned to take a liver biopsy sample as part of your clinical care.

You will receive either probiotics ("good bugs"), antibiotics (called co-trimoxazole) or placebo (a dummy sachet) for one year. You have an equal chance of each of these three treatments.

After 4, 12, 24 and 48 week's treatments, you will return to Queens's Medical Centre. We will let you know when to come. More samples (about 20mL, or four-teaspoons-full) of your blood, tummy fluid, faeces and urine will be taken. Urine collection for 24 hours will also take place at baseline and after 3 months.

You may need to come to hospital for other visits, to help look after you.

**What are my responsibilities?**
During the study you would need to take the treatment every morning. If you do forget, take it at lunchtime or later in the day.

Probiotics should be drunk after stirring the contents of 2 sachets into a cold drink such as water or orange juice (but not fizzy or hot drinks and not with hot food).

The antibiotics should be taken with any drink.

You should not be taking any other probiotics during the study (such as Yakult®). If you are prescribed any other tablets during the study then the study doctor should be told.

When you come back for your study visits please bring your study medication with you so that we can check it and give you a fresh supply.

**What other treatments are available?**
Treatment for tummy fluid can be with water tablets (diuretics) and by being careful with salt. These may still be used even if you agree to take part.

**What are the possible side-effects of taking part?**
The antibiotic co-trimoxazole can cause headache, rash, diarrhoea, pain in the muscles and feeling sick. Any new problems with treatment such as rash should be reported to the doctor at once.

Side effects from probiotics are rare, but if they do occur they tend to be mild and digestive like gas or bloating.

**What are the possible disadvantages and risks of taking part?**
You will come for regular hospital visits after 4, 12, 24 and 48 weeks during your treatment, which will take time out of your day. In patients like you, we would be seeing you regularly anyway.

This medicine should not be used during pregnancy or breastfeeding as it may be harmful to the baby. If you are pregnant or plan to become pregnant during the study you should not take part. To be sure, we will do a pregnancy test. You should also use effective contraception (like condoms) while taking part. If you become pregnant during the study you must tell the study doctor.

If you have private medical insurance, it may be affected by taking part and you should check with your insurance company before taking part.

If we discover that you have a medical condition that you did not know about before, we will tell you about it and discuss how this should be treated.

**What are the possible benefits in taking part?**
You will help us to understand better how to look after patients with liver scarring and tummy fluid better in the future.

**What happens when the research study is finished?**
If we feel that you should carry on with medication after the study ends, this will be prescribed for you.

**What if something goes wrong?**
There are no special compensation arrangements for this study. However, if you are harmed as a result of someone's negligence, then you may have grounds for a legal action for compensation, but you may have to pay your legal costs.

If you have concerns about any aspect of the way you have been treated during the study you can contact the hospital's Patient Advice and Liaison Service (PALS) on 0115 924 9924 EXT 65412 or 62301, minicom 0800 183 0204 or write to PALS, NUH NHS Trust, c/o PALS, Freepost, NEA 14614, Nottingham, NG7 1BR. If you wish to make a formal complaint, please write to Chief Executive, Dr Peter Homa at NUH NHS Trust, QMC campus, Derby Road, Nottingham, NG7 2UH.

**What if there is an emergency?**
If there is an emergency you should seek medical attention in the usual way; either through NHS direct, the emergency department or by contacting one of the study doctors (Dr Martin James 0115 9249924 Ext 63443).

**Will my taking part in this study be kept confidential?**
Your medical records may be examined by an authorized person from the clinical trial team or the regulatory authorities. This is to check the study is being carried out correctly. Your name will not be disclosed outside the hospital although with your permission, your GP will be informed you are taking part.

**What will happen to the results at the end of the research study?**
The results of this study will not be known until some time after the last patient has finished (in about one year's time). The doctor will let you know the results, and which treatment you were taking. The results may be reported in medical journals or meetings, but you will not be identified by name.

**Who is organizing and funding the research?**
This study is being designed and run by the Nottingham NIHR Biomedical Research Unit and funded by a charity research grant from Nottingham University Hospitals. The probiotic study medication and placebo (dummy) sachets are being funded by VSL#3 pharmaceuticals.

**Who has reviewed the study?**
The Nottingham Research Ethics Committee has approved this study.

**What do I do now?**
Thank you for considering taking part in this research. You will be contacted in a few days by one of the study investigators (doctor or nurse) when you can ask any questions you have and let us know whether or not you would like to take part

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