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**M**echanism of **B**etablockade **O**n bacterial translocation in **P**ortal hypertension

(MBOP study)

 **Participant Information Sheet (MBOP) – Summary**

**Contents**

**We invite you to take part in the MBOP study**

* Before you decide if you want to take part, it is important for you to understand why this research is being done, and what it will involve.
* Please take time to read this and to discuss with friends or relatives, if you wish.

**Important things you need to know**

* You are entirely free to decide whether to take part or not.
* Deciding not to take part will not affect your participation in BOPPP or your clinical care.
* You can stop taking part at any time.
* Support will be given to you throughout the study.

**Study Design**

* We want to find out if a widely prescribed beta blocker medication influences gut bacteria in patients with cirrhotic liver disease and if this is part of the clinical effect.
* We will meet with you at your usual BOPPP appointment.
* We would like you to provide blood, saliva and stool samples
* There is one additional ultra sound test on your spleen (KCH only).

Your participation could help future medical treatment in this condition.

* If you are interested in knowing more please read pages 2-4.
1. Why are we doing this study?
2. Why have I been invited? Can I say no?
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8. Will my details be kept confidential?
9. What if there is a problem?
* For further information please contact the BOPPP research team on <<INSERT DETAILS>.



**Participant Information Sheet (MBOP) – Detailed**

## Why are we doing this study?

* People with small varices have a risk of complication including fluid in the abdomen, confusion related to the liver or infections. Carvedilol, which is being investigated in the BOPPP Trial may also reduce the chance of these complications by reducing the risk of bacteria in the bowel crossing into the blood (this is called bacterial translocation).
* This study will address this important question – do beta-blockers reduce bacterial translocation in patients with cirrhosis?
1. Why have I been invited? Can I say no?
* You have been invited because you are part of the BOPPP Trial and receiving BOPPP medication. We will involve up to 600 patients who are taking part in BOPPP.
* Can you say no? Yes - it is entirely your decision whether you take part in this study.
* You will be given time to decide whether or not to take part.
* If you decide to take part, you will be asked to sign a consent form. This will stay on record in the Trial file, be noted in your medical records and a photocopy given to you to keep.
* If you decide not to take part, your normal treatment or the treatment in BOPPP will not be affected in any way and you will continue to be cared for by your normal medical team.

#### **What will happen to me if I take part**?

* At your Baseline visit and annually for three years, you will provide a sample of blood, saliva and stool. We will ask to collect approximately an additional 65ml of blood during your routine blood tests and ask you to provide saliva and stool samples.
* In some centres, only blood tests will be performed.
* In patients at King’s College Hospital we would like to measure the stiffness of the spleen using ultrasound. This is a non-invasive test where we place a probe on your abdomen.
* We will store the cells from your blood and the liquid part for future analysis. We will test for the presence of bacteria in your blood, and for the presence of chemicals that are related to infection, leakiness of the bowel or signs that the immune system is active.
* If you provide saliva or faeces, we will assess these for the type and quantity of different bacteria.

## Are there any benefits to taking part?

Although there may be no direct benefits to you for taking part in this study, the results may lead to the best treatment being offered to prevent complications in patients with cirrhosis and small varices in the future.

## Is participating in MBOP safe?

Yes. Apart from the risk of bruising or minor bleeding while having blood tests, there are no additional risks for taking part in this study. There are no risks associated with the use of ultrasound on the spleen.

1. **What happens when the study stops?**
* After the BOPPP Trial finishes, your clinical care will continue to be provided by your medical team (your Consultant and your General Practitioner) using the current standard care for patients with cirrhosis and small oesophageal varices that have not bled.
* We will ask that your samples are stored in the King’s College Hospital Liver Biobank so that they are available for other investigators in the future. If you do not wish this to happen, we will destroy your samples at the end of the MBOP study.

#### What will happen if I don’t want to carry on?

* You can withdraw from MBOP at any time without giving a reason. Please contact your research nurse or Principle Investigator using their contact details on the last page.
* However, we would like to keep in contact with you to share information about the study.
* Information collected until your withdrawal will still be used, unless you ask us not to.

####  Will my details be kept confidential?

King’s College Hospital NHS Foundation Trust is the sponsor for BOPPP and MBOP and is based in the United Kingdom. We will be using information from you and your medical records in order to undertake this study. King’s College Hospital will act as the data controller for BOPPP and MBOP. This means that King’s College Hospital is responsible for ensuring your information is stored and used properly. Your research site will keep identifiable information about you for 15 years after BOPPP and MBOP has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from BOPPP and / or MBOP, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information <https://www.kch.nhs.uk/about/corporate/data-protection>

* + - * <<Select the first or second option – remove when localising>>

<<Option 1 – When KCH is not the study site– remove when localising >> Your research site will keep your name and contact details i.e. postcode, confidential and will not pass this information to King’s College Hospital

or

<<Option 2 – When KCH is the study site– remove when localising >> your research site will keep your name and contact details i.e. postcode, confidential.

* Your research site will use this information as needed, to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study.
* Your research data will be inserted into a database that is maintained on secure servers at King’s College London and King’s College Hospital. As such, King’s College London and King’s College Hospital will act as data processors.
* Certain individuals from King’s College Hospital, King’s College London and regulatory organisations may look at your medical and research records to check the accuracy of the research trial.
* The Company providing the equipment for the ultra sound test (Echosens) may have access to your research data.
* The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details.
* There will be an open-access BOPPP trial website www.boppp-trial.org which contains information about the BOPPP trial. No identifiable personal information will be on this website.

If you wish to raise a complaint on how we have handled your personal data, you can contact your Data Protection Officer / or equivalent <<INSERT DETAILS>> who will investigate the matter. If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner’s Office (ICO).

Your details will be kept confidential during the study and your samples stored without any identifiable information on the samples. Any results from the investigations of blood, saliva or stool will not have any identifiable information attached and will not be published in a way that can identify you.

#### 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 **(see contact details below)**.
* If you remain unhappy and wish to complain formally, in England and Wales you can do this by contacting the Patient Advice and Liaison Services (PALS). In Scotland, you can contact your local hospital’s Patient Experience Team. In Northern Ireland you can contact <<INSERT DETAILS>>
* Contact details are: << INSERT LOCAL DETAILS HERE>>.
* In the unlikely event that something does go wrong and you are harmed during the research due to someone’s negligence, then you may have grounds for legal action and compensation against the Sponsor but you may have to pay your legal costs.
* The normal NHS complaints mechanisms will still be available to you, if appropriate.

**Thank you for taking the time to read this information and for considering taking part in this study.**

**If you have any questions, please contact the trial research team on** <INSERT CONTACT DETAILS HERE> **or Principle Investigator on** <INSERT CONTACT DETAILS HERE>

**Alternatively, you can contact the Chief Scientific Investigator for the MBOP study:**

Dr Mark McPhail (Senior Lecturer and Consultant Hepatologist)

Institute of Liver Studies, King’s College Hospital,

Denmark Hill, London SE5 9RS

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