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**Patient information sheet**

# MANGO Trial Patient Information Sheet

**Title: Managing Gallstone Disease in the Elderly: Comparing Quality of Life and Outcomes after Operative and Non-Operative Treatment**

**Short title: MANGO**

You are being invited to take part in a research study sponsored by the Portsmouth Hospitals NHS Foundation Trust and run by the Wessex Research Collaborative (a group of surgical trainees). Before you decide whether to participate it is important that you understand why this research is being done and what it will entail.

Please read the following information carefully and discuss it with others if you wish. Please do not hesitate to ask us if anything is unclear or you would like further information.

**Why is this study being done?**

Patient over 70 are very commonly admitted to hospital with problems caused by gallstones, such as pain, infection, jaundice and pancreatitis (inflammation of the pancreas, a digestive organ which can get blocked by gallstones). Some people have their gallbladder removed during their initial admission and others are treated first with medical therapy (such as antibiotics or an endoscopy) then brought back later to have their gallbladder removed as a planned (or “elective”) operative. This usually prevents further problems caused by gallstones. For a number of reasons, including frailty or other medical problems, surgery is not considered the appropriate treatment for some patients.

Very little is known about what happens to these patients in the longer term – such as whether the gallstones do cause more problems and how this affects their quality of life. This study aims to follow up patients who were admitted to hospital with gallstone disease to assess how this has affected them for up to three years after their initial diagnosis and compare those who did and those who did not have surgery. Patients will be contacted regularly to ask whether they have any ongoing symptoms and how this

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affects their quality of life. This is an observational study which will not affect which treatment each patient receives – this will be decided as normal by the team treating them in hospital. A better understanding of what happens to patients after surgical and non-surgical treatment would allow doctors to have more informed discussions with patients about the likely outcomes of each treatment and improve their ability to make a joint decision about whether surgery is the best option.

**The purpose of this study** is to find out more about what happens to patients who have surgery for gallstones compared to those who don't. We want to find out whether those who don't have surgery are readmitted to hospital more frequently and have more long-term problems and poorer quality of life.

**Why have you been invited?** All patients aged 70 or over who have been admitted to hospital as an emergency with gallbladder problems are being asked if they would like to take part in the study.

**Do you have to take part?** No. It is up to you whether or not you want to take part (i.e. this is "opt in" rather than "opt out"). If you decide to take part you will be given this information sheet to read and be asked to sign a consent form. If you decide to take part you are also still free to withdraw at any time and without giving a reason. A decision to withdraw at anytime, or any decision not to take part, will not affect the standard of care you receive in the future.

**What will happen to you if you take part?** Your treatment will be exactly the same whether you take part or not. We will collect information about you while you are in hospital from your medical records and then contact you by telephone 30 days, 1 year and 3 years after your admission to ask you some questions about how you are feeling, whether you have been admitted to hospital again with gallstones and about your quality of life. We may also contact your GP or access your medical notes at these timepoints in order to record details about your health relevant to the trial.

**What are the possible benefits of taking part?** There are no direct benefits to you from taking part but we hope this will help us improve the way we treat older patients with gallstones in the future.

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**What are the disadvantages of taking part?** There will be no disadvantage to you from taking part, as you will receive the same standard treatment regardless. The three follow up telephone calls should only take approximately 15 minutes each and you will not need to attend any appointments as part of the trial.

**Are there any side effects / risks?** There are no additional risks to you in this study.

**Taking part in this study will be kept confidential.** All information that is collected about you during the course of this study will be kept strictly confidential. A letter will be written to your GP to inform them of your involvement in this study.

**How will we use information about you?** We will need to use information from you, your medical records and your GP for this research project. This information will include your initials and hospital number. People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are (including the Wessex Research Collaborative) will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

**What are your choices about how your information is used?**

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- If you choose to stop taking part in the study, we would like to continue collecting information about your health from your medical records or GP. If you do not want this to happen, tell us and we will stop.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

**Where can you find out more about how your information is used?**

You can find out more about how we use your information at
www.hra.nhs.uk/information-about-patients/

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Or by contacting the Data Protection officer at :
information.governance@porthosp.nhs.uk

**What will happen to participants who give consent to take part but lose capacity during the study period?** If you develop a health problem that means you are no longer able to understand the study, the information already collected will still be included in our results, but we will not carry out any further follow up questionnaires, contact your GP or obtain any more information about you from hospital records.

**What will happen to the results of the research study?** These may be presented in regional, national or international meetings and may be submitted for publication in medical journals. The information gathered during this study will be completely anonymized and no volunteer will be individually identified.

**Will participants be informed of the results of the study?** Yes. If participants want to be informed of the results of the study they will be contacted by letter or email with the results at the end of the study. Please let us know if you would like to be kept informed when you sign the consent form. If you change your mind please contact us by phone, email or letter and we will update your preferences.

**Who is organizing the research?** This study has been organized by the Wessex Research Collaborative and is sponsored by Portsmouth Hospitals NHS Foundation Trust.

**Who is funding the research?** This study has been funded by a grant from Rosetrees Trust.

**Who has reviewed the study?** This study was reviewed and approved by our local research and development office and has received Ethical Approval from the North of Scotland 2 Research Ethics Committee.

**Contact for further information**
If you have any further questions or want further information please contact Ms Amy Lord via email on amylord@nhs.net

Thank you for reading this information sheet.

Portsmouth Hospitals University NHS Trust

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