Sultan Qaboos University Hospital

Part 1: Participant Information Sheet

Study Title: Eradication of Carbapenem-Resistant Klebsiella Pneumoniae Gastrointestinal Colonization and Prevention of Secondary Bloodstream Infections with Oral Colistin (Double blind, placebo controlled trial)

You are invited to participate in a research study conducted by researchers from the departments of medicine, microbiology, hematology, intensive care, infection control, and pharmacy at SQU. Before you decide whether or not you wish to participate in this study, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish.

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1. **What is the purpose of this study?**

   The purpose is to investigate whether oral colistin [antibiotic] eradicates extensively drug resistant bacteria [klebsiella] from the gastrointestinal tract and whether this impacts your risk for having invasive bloodstream infection by this organism.

2. **Why have I been invited to participate in this study?**

   You are eligible to participate in this study because you are colonized with this bacterium.

3. **What if I don't want to take part in this study, or if I want to withdraw later?**

   Participation in this study is voluntary. It is completely up to you whether or not you participate. If you decide not to participate, it will not affect the treatment you receive now or in the future. Whatever your decision, it will not affect your relationship with the staff caring for you. If you wish to withdraw from the study once it has started, you can do so at any time without having to give a reason.

4. **What does this study involve?**

   If you agree to participate in this study, you will be asked to sign the Participant Consent Form. This study will be conducted during your hospitalization and only up to 14 days after enrolment. Your discharge from the hospital shall not be affected by the study. Because we do not know if the test drug is better than placebo in eradicating this bacterium, we need to compare the two. To do this, we will put the participants into two groups. The groups are selected by chance. Participants in one group will be given the test drug while participants in the other group will be given the placebo. It is important that neither you nor we know which of the two you are given. This information will be in our files, but we will not look at these files until after the research is finished. This is the best way we have for testing without being influenced by what we think, or hope might happen. The healthcare workers will be looking after you and

the other participants very carefully during the study. If we are concerned about what the drug is doing, we will find out which drug you are getting and make changes.

5. **What is placebo?**

A placebo or inactive medicine looks like real medicine, but it is not. It has no effect on a person because it has no real medicine in it.

6. **What is current hospital standard for decolonization of this bacterium in patients like me?**

The current standard treatment offered in this institution and elsewhere is a "no decolonization strategy". If you agree to participate in this trial, you will then be asked to undergo the following:

- ✓ Administered oral test drug or placebo 4 times per day for 7 days.
- ✓ Have a repeat rectal swab on day 7 post completion of test drug or placebo.

7. **Are there risks to me in taking part in this study?**

Potential risks include hypersensitivity to test drug or placebo and possibly gastrointestinal side effects such as nausea, vomiting, diarrhea, and abdominal pain, and development of colistin resistance if you receive the intervention drug.

8. **What are the alternatives to participation?**

You do not have to take part in this research project to receive treatment at this hospital.

9. **Will I benefit from the study?**

This study aims to further medical knowledge and may improve future strategies to prevent invasive disease by this difficult to treat bacterium. This research intervention may also directly benefit you, but we do not know for certain at this point.

10. **Will taking part in this study cost me anything?**

Participation in this study will not cost you anything and will not affect your treatment and discharge plans.

11. **How will my confidentiality be protected?**

Any identifiable information that is collected about you in connection with this study will remain confidential and will be disclosed only with your permission. Only the researchers will have access to your details and results that will be held securely at SQUH.

12. **What happens with the results?**

We plan to publish the results. In any publication, information will be provided in such a way that you cannot be identified.

13. **What should I do if I want to discuss this study further before I decide?**

When you have read this information, one of the researchers will discuss it with you and any queries you may have.

Thank you for taking the time to consider this study.

If you wish to take part in it, please sign the attached consent form.

This information sheet is for you to keep.
