Sultan Qaboos University Hospital
Participant Information Sheet

Study Title: Eradication of Carbapenem-Resistant Klebsiella Pneumoniae Gastrointestinal Colonization and Prevention of Secondary Bloodstream Infections with Oral Colistin

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You are invited to participate in a research study conducted by researchers from the departments of medicine, microbiology, 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.

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, and we believe that this may put you at risk invasive infection by this pathogen.
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.
   New information about the treatment being studied may become available during the course of the study. You will be kept informed of any significant new findings that may affect your willingness to continue in the study.
   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 may extend for up to 35 days and may include subsequent admissions for up to 6 months. Your discharge from the hospital shall not be affected by the study.

   The treatment approach being investigated in this study differs from the standard treatment offered in this institution which is a "no decolonization

strategy". If you agree to participate in this trial, you will then be asked to undergo the following:

- ✓ Administered oral colistin 4 times per day for 7 days
- ✓ Rectal swabs will be performed on the last day of treatment (day 7), on days 14, 28 after the end of treatment, and subsequent admissions within 6 months (when applicable).

5. **Are there risks to me in taking part in this study?**
   Potential risks include hypersensitivity to colistin and possibly gastrointestinal side effects such as nausea, vomiting, diarrhea, and abdominal pain, and development of colistin resistance.
6. **What are the alternatives to participation?**
   You do not have to take part in this research project to receive treatment at this hospital.
7. **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.
8. **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.
9. **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.
10. **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.
11. **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.
