

RESEARCH CONSENT FORM



1. Title of research

Orthopedic Wound Dressing Using Sterile Versus Clean Non-sterile Techniques At Hamad General Hospital.

2. Principal Investigator

Dr. Ghalib Ahmed, Hamad Medical Corporation

3. Why are we inviting you to join this research?

The investigator and colleagues at Hamad Medical Corporation (HMC) are conducting this research.

We are inviting you to join because are including adult patients (age ≥ 18) at our orthopedic surgery ward who underwent clean elective orthopedic procedures such as joint replacement and reconstructive surgery.

Any patient that has open fractures, previously superficial or deep infection at the site of surgery, poly-trauma, transfusion of blood products, obesity (BMI $> 40 \text{ kg/m}^2$), diabetes mellitus, revision procedures or immune-compromised states will be excluded.

4. What should you know about this research?

- We will explain the research to you
- Whether or not you join is your decision (you can accept or refuse no matter who is inviting you to participate)
- Please feel free to ask questions or mention concerns before deciding, or during or after the research
- You can say yes but change your mind later
- We will not hold your decision against you

5. Who can you talk to?

If you have questions or concerns, or if you think the research has hurt you, talk to the research team at:

Dr Osama Alzobi, Orthopedic Resident, HMC. Mobile number: 70119943

If you have questions about your rights as a volunteer, or you want to talk to someone outside the research team, please contact:

- HMC-IRB Office at 4025 6410 (from Sunday to Thursday between 7:00am-3:00pm) or email at irb@hamad.qa

6. Why are we doing the research?



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This study aims to evaluate the incidence of wound infection that may occur in the following 30 days after orthopedic procedures. For each patient we will use either sterile or clean non-sterile gloves for wound care and dressing after the operation then we will compare the rate of infection between both groups.

7. How long will the research take?

We think that you will be in the research for 1 month from the time of your surgery.

We expect the research to last for 12 months.

8. How many people will take part?

We plan to study 100 people in HMC, orthopedic surgery ward.

9. What happens if you take part?

If you agree to join, we will ask you to do the following:

Following enrollment, you will be allocated randomly to one of the following treatment groups. The first group will consist of 50 patients with whom we will use sterile technique for wound care and dressing change. In the other group, which also includes 50 patients, we will use of clean non-sterile. In both groups, patients will be followed to 30 days for any sign of wound infection.

Randomization means that you are put into a group by chance. It is like flipping a coin. Neither you nor the researchers choose which group you will be in. You will have a 50% chance of being place in a specific group.

Neither you nor the researchers will know what group you are in, but we can get this information if needed for your safety.

The use of sterile technique is defined by the use of sterile field, sterile gloves, and sterile instruments.

The clean technique includes the use of a clean procedure field, clean non-sterile gloves and ensuring that the gloves, field, and supplies are free of contamination.

World Health Organization (WHO) Hand Hygiene Technique with Soap and Water will be implemented. Then the use of one pair of clean non-sterile gloves during the opening of the dressing. The skin will be disinfected with a chlorhexidine stick. Depending on the patient treatment allocation, a sterile or clean non-sterile technique will be utilized for dressing application.

You will be followed during the hospital stay 14 days and 30 days in the outpatient clinic for signs and symptoms of wound infection.

Blood will be drawn in patients who show signs and symptoms of wound infection such as (redness, pain, hotness, swelling, fever).

You will not be asked to provide any information other than your past medical and surgical history.

You will interact with our research team in the site which include a doctor and wound care nurse.

You will not be requested to come between your scheduled follow up unless you have any signs of wound infection. No long term follow-up appointments or procedures.

10. Could the research be bad for you?



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Each adverse events will be followed up until resolved with or without persistent damage or until the end of the patient's study participation. All patients experiencing an adverse events must be monitored until the symptoms subside and any clinically relevant changes in laboratory values have returned to baseline, or until there is a satisfactory explanation for the changes observed

11. Could the research be good for you?

There are no benefits to you from joining this research. However, possible benefits to others include getting better understanding of wound infection that may occur after orthopedics procedures that may influence our future practice.

12. What happens to information about you?

We will make efforts to secure information about you. This includes using a code to identify you in our records instead of using your name. We will not identify you personally in any reports or publications about this research.

We cannot guarantee complete secrecy, but we will limit access to information about you. Only people who have a need to review information will have access. These people might include:

- Members of the research team and other Hamad Medical Corporation representatives whose work is related to the research or to protecting your rights and safety
- Representatives of the Ministry of Public Health Qatar who make sure the study is done properly and that your rights and safety are protected
- Your doctors and nurses

13. What if you don't want to join?

You can say no and we will not hold it against you.

14. What if you join but change your mind?

You have the right to withdraw from the study at any time point. This will not affect their care in anyway. We will ask the withdrawing patients if we can publish and use the data we collected up to the point of withdrawal. If the patient refuses to share any of the data, we will delete it permanently.

15. What else should you know?

If you are injured as a direct result of research procedures, contact the investigator and appropriate care will be made available at HMC. If you seek care outside of HMC, such care will be at your expense. Compensation is not available in case of injury.



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Signature Page for Capable Adult

Volunteer

I voluntarily agree to join the research described in this form.

Printed Name of Volunteer

Signature of Volunteer Date

Person Obtaining Consent

I document that:

- *I (or another member of the research team) have fully explained this research to the volunteer.*
- *I have personally evaluated the volunteer's understanding of the research and obtained their voluntary agreement.*

Printed Name of Person Obtaining Consent

Signature of Person
Obtaining Consent Date

Witness (if applicable)

I document that the information in this form (and any other written information) was accurately explained to the volunteer, who appears to have understood and freely given Consent to join the research.

Printed Name of Witness

Signature of Witness Date

