Title

Addition of pre-wound closure povidone iodine wash versus direct wound closure effect on surgical site infections: A randomized controlled trial

NCT Number: Not Yet assigned

Date: 13th of June 2021

Ain Shams University Hospitals
Faculty of Medicine
Department of Surgery

Informed Consent form for Surgical Patients Selected to participate in the Clinical Trial

"Addition of pre-wound closure povidone iodine irrigation versus standard antisepsis: A randomized controlled trial"

Purpose of the research
Surgical Site infection is a common complication for up to 10% of surgical procedures. It causes more complications and greatly increases the cost of treatment. There is currently a lot of debate about the best way of preventing such infections. The purpose of our study is to find a safe, cheap and reliable way to effectively reduce surgical site infections to decrease the risk of surgical procedures and reduce the cost of treatment.

Research Intervention
This research will involve using a specific antiseptic (povidone iodine) before closing your wound and following up with you to ensure full a healthy recovery.

Participant selection
We are including all adult patients undergoing open or minimally invasive surgical procedure.

Voluntary Participation
Your participation in this research is entirely voluntary. Your participation, or lack thereof, will not affect your current treatment plan in any way shape or form.

Procedures and Protocol
As there is not sufficient evidence supporting one way of antisepsis over the other. Research is needed to compare our proposed method (povidone iodine) to the standard method, Participants taking part in this study will be divided into two groups in a completely random fashion.
Participants in one group will use the standard method of antisepsis in Ain Shams University hospital while the other group will use our proposed method of 10% povidone iodine. It is important that neither the precipitants nor the investigators know which method was used. The information will be in our files, but we will not look at these files until after the research is concluded. We will then compare the results of both groups to determine which method had better results.
In the case of an infection, Samples will be taken from the infected site and studied to determine the offending pathogen.

Description of the Process
At the end of the operation, before suturing the skin, the surgeon will irrigate the wound using a solution of povidone iodine in one group or saline in the other group then will proceed with suturing the wound. Participants will then be given a special card that allows you to follow up In Ain Shams University Hospitals Clinics free of charge where you are encouraged to seek help should any symptoms arise.
After 30 days of your operation you will be contacted by us to assess any possible complications.
In case of an infection you will be asked to come to the clinic to get a sample from the infected site.

Duration
The research will start in 2021 till the sample size is reached. You will be followed up for 30 days from the day of the operation.

Side Effects
Povidone Iodine has known complications such as local skin irritation, itching, and rash. If the participant experiences any of these symptoms it is advised to contact us immediately or visit the Ain Shams University Hospitals clinic for directions on how best to manage them.

Risks
Participants will be followed up closely and will not be exposed to any considerable risk as the intervention drug is approved for medical use with minimal side effects.

Benefits Expected to Participants
The participants will be followed up at no additional cost during their complete post-surgical follow-up period at the Ain Shams University Hospitals clinics to ensure their complete recovery**.**

Benefits to Community
Participants will take part in the process of restructuring the current practice of pre-wound closure antisepsis and could potentially reduce the current rate of surgical site infection to a much lower number thus saving thousands, if not more, of surgical patients the trouble of surgical site infections and the cost of its treatment.

Reimbursements
The intervention used (povidone Iodine) is approved for use for wound antisepsis and thus no Health insurance is needed, however in the case of any complications they will managed according to the *Standard Protocol of Risk* of Ain Shams University Hospitals

Confidentiality
Participants information will be in complete confidentiality. Participants will be identified using a coded ID and no one has the right to read your medical information except the principal investigators.

Alternatives to participating
In case of refusing to participate in this research, the participants wishes will be respected and managed according to the standard pre-wound closure antisepsis practice in Ain Shams University Hospitals.

Sharing the Results
The results of this research will be shared locally and internationally to improve the current practice of wound closure antisepsis. The results will be shared with participants after conclusion of the study. No personal information of any of the participants will be shared.

Right to Refuse or Withdraw
Any participant doesn't have to take part in this research if they do not wish to and refusing to participate will not affect the treatment in any way.

Who to Contact

This proposal has been reviewed and approved by [IRB], which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find about more about the IRB, contact [name, address, telephone number.]).

Participants Consent Approving Volunteering in a Study

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• **I have read the accompanied explanatory leaflet.**	**Yes**	**No**
• **I can withdraw from the study any time**	**Yes**	**No**
• **I know that withdrawal from the study –in case of its occurrence- would not negative effects on health care provided to me.**	**Yes**	**No**
• **I have got enough time to ask about any issue.**	**Yes**	**No**
• **I agree to participate in this study.**	**Yes**	**No**
• **My data can be used for future projects unrelated to the current study.**	**Yes**	**No**

Participant Name	
Participant Random No	
Signature of Participant	
Date	

If illiterate
I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Thumb print of participant

A copy of this ICF has been provided to the participant.

Researcher Name	
Researcher Signature	
Date	