Kindly note that this is not the IRB approved version the Original document is bilingual (English/Arabic) but this is the approved English part

Informed Consent Template for Participation in a Clinical Study

Protocol Title: Effectiveness of polyurethane foam compared with Mepilex dressing for pressure ulcer prevention in operating room: A randomized control clinical trial.

Version:1
Version: 2.0 (20-Jun-2023)

Study Sponsor: King Abdullah Medical City in Holy Capital

Chief Investigator: Ebtisam Abdellatif ebrahim

You are invited to participate in the study because you are the one that can participate according to inclusion and exclusion criteria of the research

Aims of the study:

- To evaluate the efficacy of using polyurethane foam dressing versus mepilex dressing in pressure ulcer prevention for patients in operating room.

Number of expected participants: 88

Participation is voluntary:

You are completely free to choose whether to join the study or not. If you choose not to participate in the study, your management plan will proceed according to the standard guidelines and will not be adversely affected with your decision.

Study Procedures:

If you decide to participate in this study, you will go through the following procedures

- Evaluation of the patient after surgery then day 3 and day 7 through the management of the study by the research team.
- Changing the position of the patient to reduce pressure on the sore areas.
- Follow up for the patient from 3 to 7 days.
- There is no follow-up after 7 days and the patient will have the hospital's routine care plan

Which part of the study is experimental:

Mepilex dressing is used as part of routine care. The experimental part will be the use of polyurethane foam dressing in comparison to Mepilex dressing.

Expected benefits:

There are no expected benefits that are not known about the dressings used in the study.

Expected risks:

There are no expected risks that are not known about the dressings used, and may include hypersensitivity, skin irritation and respiratory irritation.

Alternatives to participation:

Your management plan will proceed according to one of the standard treatment plans in the hospital or as decided by your treating physician.

Freedom of withdrawal:

You have the right of withdrawal from the study at any time or if you have unacceptable adverse events, cannot cope with assessment, or follow up procedures or due to any other issue without explaining the cause of withdrawal and you will not be subjected to any harm or harmful change in your treatment plan.

Study revision and approval:

This study was revised and approved by a special board of experts at KAMC (the Institutional Review Board-IRB or research ethics committee) . It was also approved by the Saudi Food & Drug Authority (FDA)

How information and results will be used:

The result of this study will be published in a scientific journal to enable patients ulcer to benefit from these results.

Confidentiality:

Your name or file number will not be used in any study document except your hospital file. Each patient will be given a code number on the study documents, so your data will be concealed from all study participants except from the treating physician. The representative of the study sponsor and **The Saudi FDA** will have the right to explore your hospital file to compare documented information with that in the study documents to ensure accuracy of study results**.**

How new information will be communicated?

Any new information related to the effectiveness of any of the drugs used will be published and a copy of the research results will be sent to the Nursing Administration to communicate with all departments. Information will be available to patients at https://clinicaltrials.gov/.

What to do if a side effect or something wrong happens:

The patient must visit King Abdullah Medical City to undergo the necessary assessments and follow up on his condition, and treatment will be provided according to the patient's need.

you have any concerns or other questions about this study, you can contact a member of the study team on the following numbers:
Name: Ebtisam Abdellatif ebrahim
Mobil: 0568067247
Telephone: Ext: ----------
Mobile:
If you have questions about your rights as a research participant, or you have comments or concerns about this study that you would like to discuss with someone other than the researchers:

You may contact the Institutional Review Board:
Telephone: 012-5549999 Ext: 18008
IRB Email: IRB@KAMC.MED.SA
OR
you may contact the Office of Human Research Protection Program if you would like to obtain information about any future research on the following numbers:
Telephone: 012-559999 Ext: 18009
Email: HRPO@kamc.med.sa

Consent statement

I hereby confirm that all aspects related to the study have been explained to me including aims and procedures and that the study (does/does not) include any experimental therapies and that my participation is voluntary with no extra-expenses and there (is/is no) payment offered to me for participation. I have been given a copy of data related to the study and a copy from this consent.

Name of Research Participant:

Signature of the participant:

Date of consent(To be personally dated by the participant)

Participant number:

Place of taking consent

Name of the participant's legal guardian and relation (if applicable)

Signature of the participant's legal guardian
(if applicable)

Date of the consent(personally dated by the participant's guardian if applicable)

Name of the Principal Investigator *(or delegate)*

Signature of the Principal Investigator *(or delegate)*

Date of the consent *(To be personally dated by the Principal Investigator or delegate)*

Name of the witness *(if applicable)*

Signature of the witness*(if applicable)*

Date of the consent *(To be personally dated by the witness*)