مستشفى الملك فيصل التخصصي ومركز الأبحاث

King Faisal Specialist Hospital & Research Centre

Gen. Org. مؤسسة عامة

Jeddah Branch - فرع جدة

Institutional Review Board (IRB)

Application for Approval of Research Proposal

RESEARCH PROPOSAL PACK

No.
Submission Date:

CONTENTS:

1. IRB RESEARCH PROPOSAL - COVER PAGE

3. **Title of Proposal: Assessing the effect of the silver dressing on surgical site infections in adult patients post cardiac surgery: a single centre randomized control trial.**	**Duration of Study:** 24 months

	Total	External Funding	Requested
BUDGET	NIL	NIL	NIL

Title of Proposal: **Assessing the effect of the silver dressing on surgical site infections in adult patients post cardiac surgery: a single center randomized control trial.**

Approval - **Departmental Research Committee:**
The Committee has reviewed this proposal and attests to its scientific validity.

Departmental Research Committee Designee	Signature	Date

Approval - Department Head(s):
I have reviewed this proposal and approve the participation of the concerned personnel of my department in it.

PARTICIPANTS	DEPARTMENTAL CHAIRMAN /UNIT HEAD	SIGNATURE

Declaration of Conflict of Interest:

All investigators must declare any potential conflict of interest with respect to this research proposal. The presence of such conflict of interest must be explained (see below). The lack of such declaration by investigators involved with this proposal is taken as evidence of the absence of any conflict of interest.

Conflict of Interest:

NAME	SIGNATURE	EXPLANATION

Principal Investigator:

Name (print Signature: _____ Date:

4. ABSTRACT

Should not exceed 200 words and should include:

- *The importance of the research topic*
- *The research hypothesis, question or statement, specific objectives and the significance of the outcome*
- *OUTLINE the methods that will be used to accomplish the research specific objectives*

Background

Prevalence of surgical site infections in cardiac surgery is about 10%. About 3% of patients who develop an SSI will die as a result. Multiple studies confirm that SSIs are a complication with significant sequelae, such as longer hospitalisation, increased health costs, increased morbidity and mortality. Hence, the prevention and management of wound infections in median sternotomy incisions after adult cardiac surgery are crucial for optimizing patient outcomes,

Aim

To assess the effect of the silver dressing on SSIs rates in adult patients post cardiac surgery.

Methodology

A single center randomized control trial approach will be employed. Adult patients admitted post cardiac surgery with a sternotomy incision will be randomized into the intervention (n=75) or control group (n=75). Units will include the cardiac surgical intensive care unit, the coronary care unit and the cardiovascular telemetry unit. Intervention will include the use of a silver dressing on the sternotomy incisions and the donors sites where applicable. The control group will follow standard care processes. Data collection will include a checklist and the modified Parsonnet Score. Data analysis will include descriptive and inferential statistics.

Conclusion

The current rate of surgical site infection amongst cardiac surgical patients is 2.1 below the benchmark of 2.9 with an operational goal of 2.1.

Principal Investigator:

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5. RESEARCH PROPOSAL: Assessing the effect of the silver dressing on surgical site infections in adult patients post cardiac surgery: a single centre randomized control trial.
Introduction *May include background information related to the research topic (Importance of the topic), the purpose in carrying out this research, and the importance of potential (expected) findings.*

BACKGROUND

Worldwide, cardiovascular diseases are considered the primary contributor to global mortality. Annually, around 18 million individuals die from these diseases, with 85% of the fatalities attributed to heart attacks (Magnussen et al., 2023). The management of cardiac diseases involves either clinical or surgical approaches. Surgical interventions are chosen when they present a greater likelihood of cardiac rehabilitation compared to clinical treatments. As a result, surgeries are quite common and necessitate meticulous planning for nursing care during the postoperative phase. This planning should be based on evidence-based practices to guarantee the delivery of high-quality care to patients. Furthermore, it aims to proactively prevent complications associated with the procedure, including the occurrence of Surgical Site Infections (SSIs)(Pivoto et al., 2010; Vieira, Stocco, Ribeiro & Frantz, 2018).

Approximately 0.5% to 3% of patients undergoing surgery will experience infection at or adjacent to the surgical incision site. Compared with patients undergoing surgery who do not have a surgical site infection, those with a surgical site infection are hospitalized approximately 7 to 11 days longer (Seidelman et al, 2023). In addition prevalence of SSI in cardiac surgery was 10% (Maleknejad 2019). About 3% of patients who develop an SSI will die as a result(Awad 2012). Multiple studies confirm that SSIs are a complication with significant sequelae, such as longer hospitalisation, increased health costs, increased morbidity and mortality(Harder et al, 2013; Predin et al 2021).

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Coronary artery bypass graft (CABG) is one of the surgical procedures for coronary artery disease (CAD) for exhibiting efficacy in reducing mortality rates and enhancing patients' quality of life (Hastalarının, 2019). Moreover, Median sternotomy is a surgical procedure involving a vertical incision through the sternum (breastbone) to access the thoracic cavity. This approach is commonly employed in various cardiac surgeries, including Coronary Artery Bypass Grafting (CABG), valve replacement, and other cardiac procedures. The median sternotomy provides direct access to the heart and great vessels, allowing surgeons to perform interventions with a clear view of the cardiac structures (King et al., 2022). Nevertheless, certain postoperative complications, including delayed healing of chest wounds and persistent incisional pain, adversely impact patients' quality of life while also extending hospital stays and elevating treatment costs.

Wound infections in adult cardiac surgical patients, particularly in the context of median sternotomy, can be influenced by various factors. Identifying and understanding these risk factors is crucial for implementing effective preventive measures (Biancari et al., 2020). Common risk factors include Diabetes Mellitus, obesity, advanced age, immunosuppression, steroid use, preoperative antibiotic prophylaxis, chronic respiratory conditions, sterilization and aseptic techniques, prolonged surgery duration, and peripheral vascular disease (Vieira, Stocco, Ribeiro & Frantz, 2018).

In fact, the prevention and management of wound infections in median sternotomy incisions after adult cardiac surgery are crucial for optimizing patient outcomes, minimizing healthcare costs, and preserving the overall quality of life for individuals undergoing this cardiac surgical procedure (Phoon & Hwang, 2020). Vigilant postoperative care and evidence-based interventions play a key role in achieving these objectives.

Wound dressings play an important role in preventing infections by creating an optimal environment for wound healing and protecting the surgical or injured site from microbial contamination (Oliverius et al., 2021). The primary functions of wound dressings in infection prevention include barrier Protection, moisture management, absorption of exudate, antimicrobial properties, promotion of granulation tissue, reduction of biofilm formation, and promotion of oxygenation (Oliverius et al., 2021).

Effective selection and application of wound dressings depend on various factors, including the type of wound, its stage of healing, and the patient's specific needs. Healthcare professionals should assess wounds, choose appropriate dressings, and monitoring for signs of infection

throughout the healing process (Slamborova et al., 2013). Silver dressing is an example of wound dressings that are impregnated or coated with silver or silver-containing compounds. The incorporation of silver in wound dressings is based on the antimicrobial properties of silver ions, which have been recognized for their ability to inhibit the growth of bacteria, fungi, and some viruses.

Many silver dressings are engineered to provide a controlled and sustained release of silver ions over time. This feature ensures a prolonged antimicrobial effect while minimizing the risk of cytotoxicity to healthy cells (Slamborova et al., 2013). Furthermore, although silver dressings are often utilized in the management of chronic wounds, such as diabetic ulcers, pressure ulcers, and venous leg ulcers, however, it can be applied to surgical wounds, including incisions from procedures such as cardiac surgery (e.g., median sternotomy), to reduce the risk of Surgical Site Infections (SSI) (Abbaszadeganet al., 2017). Their antimicrobial properties aid in controlling bacterial load and promoting wound healing. Silver dressings can also help minimize wound-related odors associated with bacterial colonization. This is particularly relevant in wounds with high exudate levels (Woodmansey &Roberts, 2018; Cooper & Kirketerp-Moller, 2018).

These characteristics make silver dressings a valuable tool in the prevention and management of infections in various types of wounds. Silver dressings come in various forms, including gels, foams, films, hydrocolloids, and nanocrystalline dressings. The importance of silver ions in the treatment of chronic and especially infected wounds has been demonstrated in many studies (Woodmansey &Roberts, 2018; Cooper & Kirketerp-Moller, 2018; Dissemond et al., 2017; Li et al., 2017; Walker & Parsons 2014). For example, in 2022, a study was conducted on 218 patients to assess the incidence of incisional surgical site infection and primary healing after general surgery procedures (Lawrie et al., 2022). The study showed that the surgical site infection (SSI) and primary incision healing were reported in 10 (9.2%) versus 21 (19.3%) ($p = 0.037$) and in 95 (87.2%) versus 86 (78.9%) ($p = 0.107$) patients treated with and without silver-based dressing, respectively. Therefore, silver-based dressing demonstrated a lower incidence of incisional SSI and improved primary healing in comparison with patients in whom conventional non-silver–based dressing has been used (Lawrie et al., 2022).

While silver dressings offer significant benefits in wound management, their effect on median sternotomy wound infections in adult patients undergoing cardiac surgery grafting at KFSHRC did

not report it. Therefore, t**he aim of this stud**y is to assess the effect of the silver dressing on SSIs rates in adult patients post cardiac surgery.

Objectives

1. Assess the effectiveness of the silver dressing on SSIs rates as compared to the standard dressing- Mepilex foam dressing in reducing SSIs.

Methodology

May include: 1. Inclusion Criteria and Exclusion Criteria, which will be used in selecting the research participants; 2. Registration, 3. Randomization Process, 4. Data gathering methods, 5. Procedures, Designated Central Laboratories, 6. Follow-up, 7. Safety and Efficacy Parameters, 8. Expected Outcome, 9. Sample Size, and 10. Statistical Methods.

Research Design

A single centre randomised control study approach will be followed.

Research Setting and study population

King Faisal Specialist Hospital and Research Center- Jeddah, a specialist referral and research center, which is a 390 bedded facility with three main domains of care namely Ambulatory Care (20 units), Nursing Speciality (13 departments), and Nursing General Services (10 departments). Patients admitted to Cardiac surgical intensive unit (CSICU), Coronary Care Unit (CCU) and Cardiovascular Telemetry- Adult (CVT Adult) Unit after cardiac surgery with a sternal wound.
In 2023 there was a total of 150 of adult cardiac patients admitted post cardiac surgery with a mediastinal incision.

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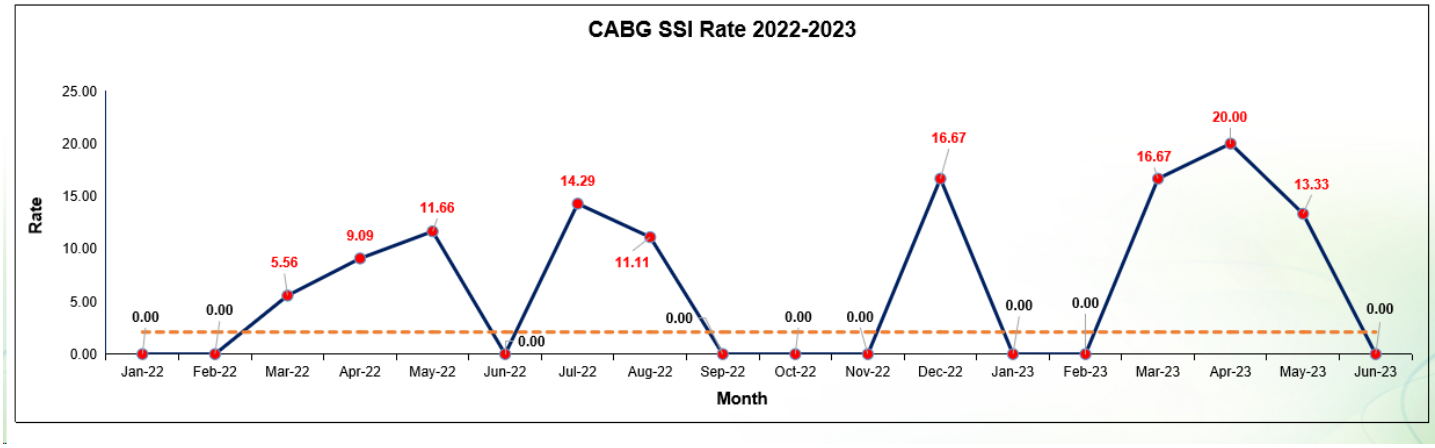
Current cardiac SSI rates at KFSHRC-J

SSIs currently are a challenge amongst cardiac surgical patients. The operational benchmarking for SSIs is 2.9 with an operational goal of 2.1. and with the current numbers of SSIs the organisation was not able to outperform the benchmark. The below graph depicts the rates of SSI for the years 2022-2023.

Category	Benchmark	Operational Goal	Year to Date (2023)			Year to Date (2022)		
			No. of Procedures	No. of Infections	Rate	No. of Procedures	No. of Infections	Rate
CABG	2.9	2.1	69	4	5.8	134	8	5.97
All cardiac		2.1	327	4	1.2	734	11	1.5



Despite defined interventions to reduce SSIs such as the ***Bundle of Care Interventions for the Prevention of Healthcare associated infections- CIPP 8834 - SSI Prevention Bundle***, the SSI rates for CABG and cardiac have soared in the latter part of 2023.

Sampling technique

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The study will follow a randomised sampling approach. Randomisation will include: first patient transferred from OR to the CSICU will be part of the intervention group, second patient part of the control group. This sequence will be followed until the required sample size is reached.

Sample size will include:

In the year 2023 there were a total of 200 patients admitted for a cardiac surgical procedure requiring a mediastinal incision. Based on this population and sample size calculation- a total of 109 patients will be included – meeting the inclusion and exclusion criteria.

Ie 55 in the intervention group and 54 in the control group.

Inclusion criteria

- Patients 14 years of age and older scheduled for cardiac surgery requiring a sternotomy incision.

Exclusion criteria

- Presence of a concurrent infection and any systemic antibiotic other than those used for the purpose of perioperative prophylaxis.
- Patients who died without an infection within 30 days following surgery.
- Patients who had undergone another procedure through the same incision(s) within a year after enrollment in this study.
- Patients who are a redo- such as needing debridement or an infection.
- Patients that have an open chest
- Patients on ECHMO
- Patients excessively bleeding
- Patients who require the surgery as an emergency
- Patients with a known allergy to silver dressings

Current Practice

Pre- operative

- 2% Chlorhexidine bathing on the night before and morning of the operation
- Hair removed by clipping or other means of removal not more than one day prior to surgery
- Prophylactic antibiotic : Cefazolin 1g

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Name (print **Signature: _____** **Date:**

- Blood glucose assessment -Insulin infusion protocol shall be initiated on unit for patient's high blood glucose level >11.mmol (<200mg/Dl).

Intraoperative

- 2% chlorhexidine and 70% alcohol based solution for skin preparation shall be used immediately prior to incision
- Appropriate prophylactic antibiotic shall be administered as per formulary
- Glycemic control shall be maintained at blood glucose levels of <11 mmol (<200mg/Dl)
- Patient Normothermia (> 36 centigrade) shall be monitored and maintained
- Antimicrobial re-dosing

Postoperative

- Glycemic control shall be maintained at blood glucose levels of <11 mmol (<200mg/Dl)
- Prophylactic antimicrobials (if prescribed) shall be discontinued after 48 hours of surgery.
- Wound dressing assessed for dry and intact
- Wound dressing is Mepilex Foam dressing

The current practice related to choice of wound dressing is the Mepilex foam boarder, however the institution is in the process of introducing the silver dressing as part of standard practice. The silver dressing has been approved by the products co-ordinator in the organisation

(Bundle of Care Interventions for the Prevention of Healthcare associated infections- CIPP 8834)

Length of stay:

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Patients' typical length of stay:

- CSICU- 2.5-3.7 day
- CCU- 2
- CVT- 3 days

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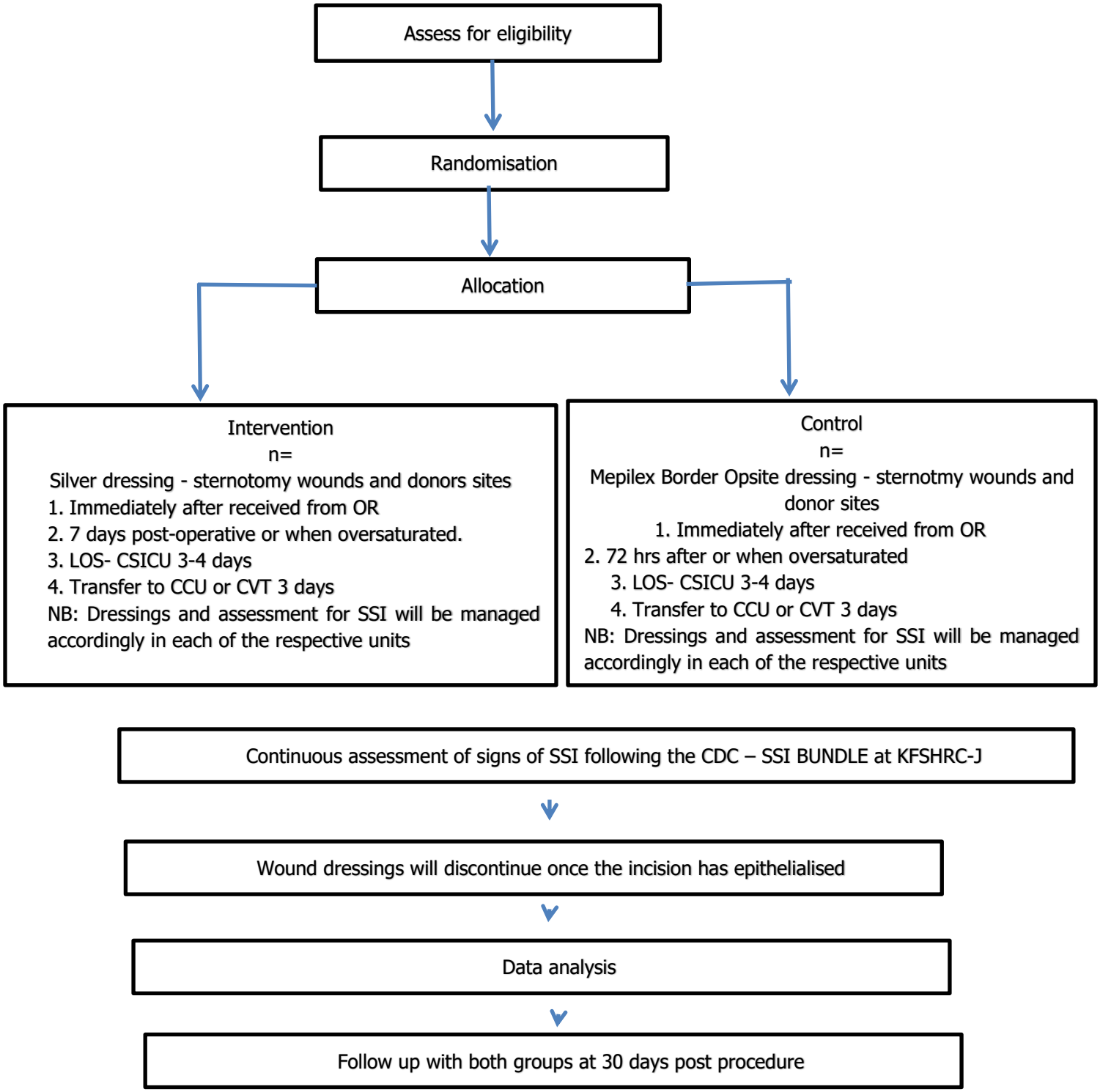
INTERVENTION



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Description of intervention

Intervention will consist of a replacement of the sterile plain postoperative dressing Mepilex border dressing (versatile five-layer all-in-one bordered foam dressing) with the sterile silver-impregnated dressing on 3 units: the CSICU, CVT. The dressing will be applied upon arrival in the CSICU directly on the incision after closure had been performed with sutures and/or staples and the Mepilex border. Dressings will be changed at seven (days) post-surgery (or sooner if oversaturated), and then changed whenever the dressing becomes saturated. Application of the dressing will be discontinued when the incision had epithelialized. There will be no changes in techniques or patient care, and no other changes of any kind (including surgeons) during the entire study period. Throughout the entire period of hospitalization, patients will be monitored for signs and symptoms of infection as per Center for Disease Control [CDC] guidelines ie is superficial, deep, organ space infection (CDC, 2010). Patients will be followed for signs and symptoms of SSIs up to one **month** following surgical intervention. Surgical site infections will be identified through assessment present in chart reviews, clinic visits, readmission to a hospital, laboratory culture surveillance, and telephone interviews at the one month period.

NB: The control group will have the Mepilex foam dressing. All other processes and care will be the same as the intervention group.

Data collection will include a check-list with:

1. Demographic
2. Risk factors
3. Antimicrobial prophylaxis pre, intraoperative and post-operative.
4. Signs of wound infection following the CDC criteria
5. Type of dressing
6. Vital signs
7. Severity of illness using Parsonnet score

The checklist apart from the Parsonnet Score Checklist was developed by the research team.

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The Modified Parsonnet Score checklist was developed as a preoperative score for adult cardiac surgery. The checklist is a validated, additive scoring system for predicting operative mortality risk in cardiac surgery (Parsonnet et al, 1989). See appendix 1; Checklist for Data collection

Data analysis

Data analysis will be done using SAS software Descriptive statistics will include frequencies and percentages. Comparisons between the 2 groups will include chi-square statistic for categorical variables and the t test for continuous variables. Logistic regression will be used to compare the risk of infection according to type of dressing and adjusting for patients' characteristics.

Ethical considerations

Data will be collected after the necessary approval from Nursing Affairs and the Institutional Review Board. Participation in this study is voluntary and no incentives will be given for participating. Participants are free to withdraw from the study at any point without penalty or risk to the treatment they were entitled to. Information regarding this research study will be offered to the participants in the study both verbally and in the form of an information document and informed consent. All participants in the research study will be selected according to research requirements and treated equally and fairly throughout their participation. Right to privacy and anonymity will be maintained by not linking any personal identification to any of the checklists and all research information will not be traceable back to individuals. Only the researchers will have access to the data, which will be kept on a computer with a password and will be destroyed after five years.

Principal Investigator:

Name (print Signature: _____ Date:

Principal Investigator:

Name (print Signature: _____ Date:

5. WORK PLAN AND RESPONSIBILITIES

A detailed description of the protocol work plan is mentioned in the original documentation. Please refer to the submitted documents. The following Table summarizes the job responsibilities of involved members:

6. REFERENCES (comprehensive literature review)

Centres for Disease Control and Prevention. (2010). National Healthcare Safety Network: surgical site infection (SSI) event. 2014-01-01 [2014-03-25]. http://www, cdc. gov/nhsn/pdfs/psc-manual/9pscssicurrent, pdf.

Cooper R, Kirketerp-Moller K.(2018). Non-antibiotic antimicrobial interventions and antimicrobial stewardship in wound care. J Wound Care, 27(6):355-377. https://doi.org/10.12968/ jowc.2018.27.6.355.

Dissemond J, Bottrich JG, Braunwarth H, Hilt J, Wilken P, Munter KC. (2017). Evidence for silver in wound care—meta-analysis of clinical studies from 2000-2015. J Dtsch Dermatol Ges., 15(5):524-535. https://doi.org/10.1111/ddg.13233.

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Principal Investigator:

Name (print **Signature: _____** **Date:**

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Parsonnet, V., Dean, D., & Bernstein, A. D. (1989). A method of uniform stratification of risk for evaluating the results of surgery in acquired adult heart disease. Circulation, *79*(6 Pt 2), I3-12.

Phoon, P. H. Y., & Hwang, N. C. (2020). Deep sternal wound infection: diagnosis, treatment and prevention. *Journal of cardiothoracic and vascular anesthesia*, *34*(6), 1602-1613.

Principal Investigator:

Name (print **Signature: _____** **Date:**

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Walker M, Parsons D. (2014). The biological fate of silver ions following the use of silver-containing wound care products—a review. Int Wound J., 11(5):496-504. https://doi.org/10. 1111/j.1742-481X.2012.01115.x.

Principal Investigator:

Name (print Signature: _____ Date:

7. BUDGET SHEET

PERSONNEL (NAME)	POSITION ON PROJECT	% TIME	GR/STEP	YEAR 1	YEAR 2
A) total for personnel:				SR	SR

EQUIPMENT *(use a separate sheet if required)*	YEAR	
B) total for equipment:	SR	SR

SUPPLIES AND MATERIALS *(use separate sheet if required)*	YEAR	
C) Total for materials and supplies:	SR	SR

other expenses *(use separate sheet if required)*		AMOUNT	
category	purpose		
D) Total for other expenses:		SR	SR

TOTAL BUDGET (A ➔ D)	SR	SR

Suggested Sources of External Funding

Company	Address	Relationship to research proposal
None		

Principal Investigator:

Name (print Signature: _____ Date:

8. Pharmacy Information Sheet *(page 1 of 2)*

Title of the Proposal:

IRB #: (if available) _____ Principal Investigator: _____

Drug Name										
	Rou	Exp	Rou	Exp	Rou	Exp	Rou	Exp	Rou	Exp
Dose										
Administration Route										
Administration Frequency										
Length of Treatment										
Drug Status*										
Number of Patients										
Provider: Hospital or Sponsor (Identify sponsor)										
Total Drugs Required (Pharmacy will calculate)										
(For Pharmacy Use) medication Cost	Rou	Exp	Rou	Exp	Rou	Exp	Rou	Exp	Rou	Exp
Research Pharmacist time					_____ (hrs) X		_____ SR/hr		= SR _____	

2 If this is a randomized study, who is responsible for Randomization?

_____

3 Over what period of time do you intend to accrue the patients?

* The Pharmacy Department must seek approval through the MOH in order to import drugs. Approval of the proposal by the IRB does not guarantee that the drugs will be approved by the MOH. Being a registered or investigational drug in any of the five reference countries (USA, Canada, UK, Sweden, Saudi Arabia) would help in obtaining MOH approval.

Please use the following abbreviations: **HF** – on Hospital formulary; **MOH** – registered by the Saudi Ministry of Health; **USA** – registered in USA; **CA** – registered in Canada; **UK** – registered in UK; **SW** – registered in Sweden; **USAI** – being investigated in USA; **CAI** – being investigated in Canada; **UKI** – being investigated in UK; **SWI** – being investigated in Sweden.

Principal Investigator:

Name (print Signature: _____ Date:

PHARMACY INFORMATION SHEET (page 2 of 2)

Title of the Proposal: _____

_____

IRB#: (if available) _____ **Principal Investigator:** _____

This part is to be completed by the Pharmacy Department:
(Check (✓) appropriate box(es) and complete)

☐ The Pharmacy Department has assigned a Research Pharmacist to provide information and assistance in the conduct of this proposal. If you have any questions, please call the Office of the Institutional Review Board at extension 2984.

The Pharmacy department will provide the following:

I. Drug keeping and dispensing
II. Preparation of Drug
III. Drug Information (physician, nurse, pharmacist, *etc*)
IV. MOH permit for import, release from customs
V. Patient counseling for drug information, compliance, medication handling, and return of unused products (if required)
VI. Maintain and submit to IRB, upon completion/termination of the study, investigational drug records of:
    (a) inventory, delivery to KFSH&RC: Date, amount, lot #, expiration date, *etc.*
    (b) use by each study subject
VII. Follow the trial randomization procedure
VIII. Supply the drugs listed on page 1 of this form

☐ Pharmacy Department will be happy to provide the above, provided the following issues have been satisfactorily addressed:

1.
2.
3.

☐ The Pharmacy Department will not be able to assist with this project due to the following:

_____

_____

☐ Total Pharmaceutical cost (routine care) _____ *SR* Total Pharmaceutical cost (experimental) _____ *SR*

This form page completed by:

NAME (PRINT) _____ SIGNATURE: _____ DATE: _____

APPROVED BY: _____ SIGNATURE: _____ DATE: _____
(Head of Pharmacy Department)

Title of the Proposal:

Does the proposed research involve any toxic chemical?

1. **Please name chemicals and describe the nature of the hazard involved:**

_____

_____

2. **Does the proposed research involve any hazardous micro-organism?**

If yes, name the organisms and describe the nature of hazards expected.

_____

_____

Also describe facilities, safety measures and procedures to protect personnel and environment.

_____

_____

3. **Does the proposed research involve radioactive materials?**

If yes, describe the materials, half-life and methods of disposal and personnel protection.

_____

_____

4. **Does the proposed research involve recombinant DNA?**

If yes, are you familiar with NIH guidelines and do you have the containment facilities? _____

Describe the nature of genes to be cloned, organisms and plasmids to be used.

_____

_____

10. Informed Consent

☐ for research involving the administration of drugs, use of devices

Principal Investigator:

Name (print **Signature: _____** **Date:**

or performance of procedures

☐ for research with no direct benefit to participant

Principal Investigator:

Name (print **Signature: _____** **Date:**