Official Title of the Study:
A Randomized Controlled Study Investigating the Effectiveness of Intravenous Dexamethasone Prophylaxis in Preventing Post-operative Urinary Retention in Spinal Anesthesia at Al-Makassed Hospital

NCT Number:
NCT07077850

Date of Document*:*
01/07/2025

Al-Quds University – Research Ethics Committee

RESEARCH ETHICS CHECKLIST

Instructions for applicants:

This checklist should be completed for every research project which involves human participants and including personal, medical or otherwise sensitive data or methodologically controversial approaches. ***This checklist must be completed before potential participants are approached to take part in any research.*** The research ethics review process is not designed to assess the merits of the research project in question, but is merely a tool to ensure that ethical considerations have been fully considered and ethical issues have been properly dealt with when arise.

Before completing this form, please read the Code of Good Practice in Research of Al-Quds University and the Ethical principles for medical research involving Human subjects (the most recent version of the Helsinki Declaration). The principal investigator and, where the principal investigator is a student, the **supervisor**, are responsible for exercising appropriate professional judgment in this review.

Complete all sections of this checklist as accurate as possible. After completing sections I to IV, check the following: If all items in the Declaration in section III are ticked AND if you have answered NO to all questions in section IV (questions 1-14), send the completed & signed copy of this form to the Head of your faculty/center/institute and a copy to the REC office for information. You may proceed with the research project but you should follow any subsequent guidance or requests from the faculty/centre/institute or your supervisor where appropriate. Undergraduate and postgraduate students should retain a copy of this form and submit it with their research report or thesis (bound in the appendix). Also graduate students should submit a copy of this form to the Deanship of Graduate Studies (DGS) when seeking registration for thesis' defense (Forms 5 & 6 of DGS). **Work which is submitted without the fully completed copy of this form will be returned unassessed or cannot complete the defense of their thesis.**

If ANY of the items in the Declaration in section III are not ticked AND / OR if you have answered YES to ANY of the questions (1-13) in Section IV, you will need to describe more fully in Section V of this form below how you plan to deal with the ethical issues raised by your research. This does not mean that you cannot do the research project, only that your proposal will need to be approved by the faculty/centre/institute or REC. After completing section V as described in the above paragraph, submit a copy of this form with properly filled section V to the faculty/centre/institute and REC office along with the Application form.

If you answered YES to ***question 14***, you will also have to submit an application to the appropriate external health authority ethics committee, after you have received approval from the faculty/centre/institute or REC office.

Section I: Applicant details

1. Name of General Supervisor	Dr. Mohammed Maree
1a. Name of principal investigator (applicant):	Dr. Abeer Dar Hasan

1b. Associated investigators:	Dr. Ahlam Hammoudeh Dr. Islam Khairaldin Dr. Majdi Abu Daoud Dr. Mohammad Qino Dr.Amani Bashar Dr.Osama Sawalha Dr.Khaled Alshawa Anas Barabrah Tareq Jarrar
2. Status (please click to select):	**Staff**, graduate student, undergraduate student
3. Email address:	abee.9.1994@gmail.com
4a. Contact address:	Jerusalem, Palestine
4b. Telephone number:	00972534541877

Section II: Project details

5. Project title:	the Effectiveness of Intravenous Dexamethasone Prophylaxis in Preventing Post-operative Urinary Retention in Spinal Anesthesia at Al-Makassed Hospital

Section III: For Students only:

6. Course title and module name and number where appropriate faculty/centre/institute:	-
7. Supervisor's or module leader's name:	
8. Email address:	
9. Telephone extension::	

Declaration by researcher (please tick the appropriate boxes)

☑	I have read the Code of Good Practice in Research of Al-Quds University
☑	The topic merits further research
☑	I have the skills to carry out the research
☑	The participant information sheet, if needed, is appropriate
☑	The procedures for recruitment and obtaining informed consent, if needed, are appropriate
☑	The research is exempt from further ethics review according to current University guidelines

Comments from researcher, and/or from postgraduate student:

Section IV: Research

Please answer each question by ticking the appropriate box:

		YES	**NO**
1.	Will the study involve participants who are particularly vulnerable or who may be unable to give informed consent (e.g. children, people with learning disabilities, emotional difficulties, problems with understanding and/or communication, your own students)?		☑
2.	Will the study require the co-operation of a gatekeeper for initial access to the groups or individuals to be recruited (e.g. students at school, members of self-help group, and residents of nursing home)?		☑
3.	Will deception be necessary, i.e. will participants take part without knowing the true purpose of the study or without their knowledge/consent at the time (e.g. covert observation of people in non-public places)?		☑

4.	Will the study involve discussion of topics which the participants may find sensitive (e.g. sexual activity, own drug use)?		☑
5.	Will drugs, placebos or other substances (e.g. food substances, alcohol, nicotine and vitamins) be administered or ingested by participants or will the study involve invasive, intrusive or potentially harmful procedures of any kind?		☑
6.	Will blood or tissue samples be obtained from participants?		☑
7.	Will pain or more than mild discomfort be likely to result from the study?		☑
8.	Could the study induce psychological stress or anxiety or cause harm or negative consequences beyond the risks encountered in normal life?		☑
9.	Will the study involve prolonged or repetitive testing?		☑
10.	Will financial inducements (other than reasonable expenses and compensation for time) be offered to participants?		☑
11.	Will participants' right to withdraw from the study at any time be withheld?		☑
12.	Will participants' anonymity be compromised or their right to anonymity be withheld or information they give be identifiable as theirs?		☑
13.	Might permission for the study need to be sought from the researcher's or from participants' employer?		☑
14.	Will the study involve recruitment of patients or staff through the National Health Information System, (NHIS)?		☑

Section V: Addressing ethical problems

If you have answered YES to any of questions 1-13 please complete below and submit this form to your faculty/centre/institute or REC.

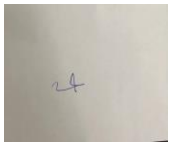
Project title

Principal investigator/student

Supervisor (if principal investigator)

Summary of issues and action to be taken to address the ethics problem(s)

Please note that it is your responsibility to follow the Code of Good Practice in Research of Al-Quds University and any relevant academic or professional guidelines in the conduct of your research project. **This includes providing appropriate information sheets and consent forms, and ensuring confidentiality in the storage and use of data**. Any significant change to the design or conduct of the research should be notified to the faculty/centre/institute or REC office and may require a new application for ethics approval.



Signed: _____ Principal Investigator

Makassed Hospital
Dr.Mohammed Maree
General &laparoscopic Surgeon

Approved: _____ Supervisor or module leader (where appropriate)

Date: 10/02/2024

For use by faculty/centre/institute or REC office:

- No ethical problems are raised by this proposed research - **Retain this form on record**

- Appropriate action was taken to maintain ethical standa ds

- The research protocol should be revised to eliminate the ethical concerns or reduce them to an acceptable level, using the attached suggestions.

- Please submit faculty/centre/institute application for Ethics Approval

- Please submit REC Application for Ethics Approval

Retain this form on record and return a copy of section V to Researcher

Signed: _____

Date: _____