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

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1. Project Title (in full)

Effectiveness of Intravenous Dexamethasone Prophylaxis in Preventing Post-operative Urinary Retention in Spinal Anaesthesia at Al-Makassed Hospital

RESEARCH PERSONNEL

General Supervisor

Name	Dr. Mohammed Maree
Title	General surgeon
Qualifications	MD
University Position Held: employee, affiliate (indicate type; eg. honorary associate, clinical academic), visiting	clinical academic Faculty of Medicine Al-Quds University
Full mailing address	Ramallah, Palestine
Telephone	00972592309896
Fax	-
E-mail	mohammedmaree1983@gmail.com

Principal Investigator

Name	Dr. Abeer Dar Hasan
Title	Resident doctor – surgery
Qualifications	MD

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University Position Held: employee, affiliate (indicate type; eg. honorary associate, clinical academic), visiting	-
Full mailing address	Jerusalem, Palestine
Telephone	00972534541877
Fax	-
E-mail	abee.9.1994@gmail.com

Associate Investigator(s)

Associate Investigator 1	
Name	Dr. Ahlam Hammoudeh
Title	Resident doctor – anesthesia
Qualifications	MD
University Position Held: employee, affiliate (indicate type eg honorary associate, clinical academic), visiting	-
Full mailing address	Jerusalem , Palestine
Telephone	00972595744577
Fax	-
E-mail	ahlamhammoudeh123@yahoo.com

Associate Investigator 2	
Name	Dr. Islam Khairaldin
Title	Resident doctor – anesthesia
Qualifications	MD

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University Position Held: employee, affiliate (indicate type eg honorary associate, clinical academic), visiting	-
Full mailing address	Jerusalem , Palestine
Telephone	00972533491136
Fax	-
E-mail	islamkhairaldeen@gmail.com

Associate Investigator 3	
Name	Dr. Majdi Abu Daoud
Title	Resident doctor – surgery
Qualifications	MD
University Position Held: employee, affiliate (indicate type eg honorary associate, clinical academic), visiting	-
Full mailing address	Bethlehem, Palestine
Telephone	00972595414606
Fax	-
E-mail	majdi.aziz1998@gmail.com

Associate Investigator 4	
Name	Dr. Mohammad Qino
Title	Resident doctor – surgery
Qualifications	MD
University Position Held: employee, affiliate (indicate type eg honorary associate, clinical academic), visiting	-
Full mailing address	Jerusalem, Palestine

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Telephone	00972597484208
Fax	-
E-mail	M.qinoo@gmail.com

Associate Investigator 5	
Name	Anas Barabrah
Title	Medical Student
Qualifications	undergraduate
University Position Held: employee, affiliate (indicate type eg honorary associate, clinical academic), visiting	Medical Student Faculty of Medicine Al-Quds University
Full mailing address	Ramallah, Palestine
Telephone	0597159258
Fax	-
E-mail	anasmufeed3@gmail.com

Associate Investigator 6	
Name	Tareq Jarrar
Title	Medical Student
Qualifications	undergraduate
University Position Held: employee, affiliate (indicate type eg honorary associate, clinical academic), visiting	Medical Student Faculty of Medicine Al-Quds University
Full mailing address	Ramallah, Palestine
Telephone	00972595076137
Fax	-
E-mail	tareq.jarrar2@students.alquds.edu

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Associate Investigator 7	
Name	Amani Ahmed
Title	Resident doctor-Surgery
Qualifications	MD
University Position Held: employee, affiliate (indicate type eg honorary associate, clinical academic), visiting	-
Full mailing address	Jerico, Palestine
Telephone	00972569045086
Fax	-
E-mail	amanibashar243@gmail.com

Associate Investigator 8	
Name	Osama Mohammed Sawalha
Title	MD
Qualifications	Anaesthesiologist
University Position Held: employee, affiliate (indicate type eg honorary associate, clinical academic), visiting	-
Full mailing address	Tulkarem , Palestine
Telephone	00972598603554
Fax	-
E-mail	modosawalhajr@gmail.com

Associate Investigator 9	
Name	Khaled Nassed Alshawa
Title	MD ,MRCS

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Qualifications	General Surgeon
University Position Held: employee, affiliate (indicate type eg honorary associate, clinical academic), visiting	Clinical Lecturer Faculty of medicine Azhar University
Full mailing address	Gaza, Palestine
Telephone	00972599335031
Fax	-
E-mail	khaledshawa@gmail.com

PROJECT AND SITE DETAILS

2. Please provide details of the research setting (Research laboratory, Hospital, etc)

This research project will be done at Al-Makassed Hospital by surgery, anaesthesia doctors, and undergraduate medical students. Data will be collected verbally in the surgery department by resident doctors.

3. Provide information to demonstrate that the researchers involved in the project have the necessary training, expertise and experience to carry out their role in the research.

This research will be supervised by Dr. Mohammad Maree and sponsored by AMRA. All authors had enrolled in previous similar research projects. Most of the research team completed the following modules from TRREE:
Module 1: Introduction to Research Ethics
Module 3: Informed Consent
Module 3.2: Good Clinical Practice

4. Please outline (or attach) the proposed procedure for dealing with any health emergencies that may arise during the conduct of the research. If the Principal Investigator at the proposed University site is

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not a health practitioner, please provide details of the medical practitioner who will be responsible for dealing with medical emergencies.

The team consists of general surgery specialists and well-trained doctors. Therefore, if any emergency occurs during the research process, they will deal with it.

5. Risk assessment (please indicate that the following are accurate):

   ☑ The site has adequate data protection and security systems to ensure protection of participant's privacy

   ☑ The site has adequate, secure systems for storage of investigational products

   ☑ Participants are able to report adverse events and study outcomes reliably

6. Is this research at the University site commercially sponsored?

   ☑ NO

   ☐ YES – please provide a copy of the certificates

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DECLARATION BY INVESTIGATORS

I confirm that I have read and understand the attached Code of Good Practise and Helsinki declaration in Research Conduct in Human Research.

I confirm that I have read and understand the Code of Good Practise and Helsinki declaration in Research Conduct in Human (Provided and declared by the Ethics Research Committee, Al-Quds University)

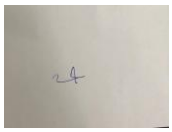
I confirm that the above information is accurate, and that the project will continue in accordance with the Human Research Ethics Committee approved protocol.

General Supervisor

Makassed Hospital
Dr.Mohammed Maree
General &laparoscopic Surgeon

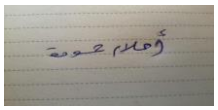
Dr. Mohammed Maree		10/02/202
Name	*Signature*	*Date*

Principal Investigator

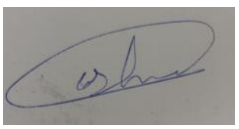


Dr. Abeer Dar Hasan		10/02/202
Name	*Signature*	*Date*

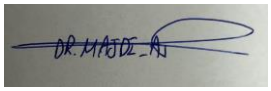
Associate Investigator(s)



Dr. Ahlam Hammoudeh		10/02/202
Name	*Signature*	*Date*



Dr. Islam Khairaldin		10/02/202
Name	*Signature*	*Date*



Dr. Majdi Abu Daoud		10/02/202
Name	*Signature*	*Date*

10/02/202

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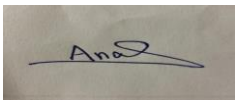
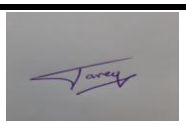
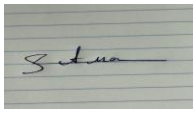
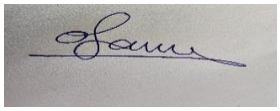
Name	Signature	Date
Dr. Mohammad Qino		
Anas Barabrah		10/02/202
Tareq Jarrar		10/02/202
Amani Ahmed		10/06/202
Osama Sawalha		10/02/202
Khaled Alshawa		10/02/202

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SECTION 1: ADMINISTRATION

1.1

(a) **Provide a brief summary of the project in non technical language (approximately 100 words)**

This research is going to investigate the efficacy of administering intravenous dexamethasone in preventing post-operative urinary retention in patients going under regional and general anesthesia for any type of general surgery operation. The study population will be adult males. Any patient who has a contraindication to dexamethasone or is known to have a pre-existing urologic condition will be excluded. The participants will be divided into two groups (active drug and placebo). At the end, the study will compare the outcomes between both groups.

(b) Outline the academic/scientific merits of this study (including potential contributions to the body of knowledge and methodological rigor) (approximately 100 words)

Postoperative urinary retention is a significant and frequent postoperative complication. This study could have a huge impact on dealing with these cases in clinical practice, especially since it will include a large sample size and deliberate randomization.

1.2 (a) Has this project already been submitted to any other HREC(s)? ☐ **N** ☑ **Y**

(b) Will this project be submitted to any other HREC(s)? ☑ ☐

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N **Y**

If you answered YES to (a) or (b), give the name of the HREC(s)

The ethics committee of Al-Makassed Hospital

1.3 (a) Indicate the proposed date of commencement of the project.

Projects should not commence without the prior written approval of the REC.

Date July 2025

(b) Indicate the proposed completion date of the project.

Date Jan 2026

1.4 (a) Has this protocol received research funding/contracting or is this submission being made as part of an application for research funding/contracting? **N** ☑ **Y** ☐

If you answered YES, list the funding/contracting bodies to which you have submitted, or intend to submit, this project. Attach a copy of the grant application(s), contract(s) or similar agreement(s).

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Funding/Contracting body 1:

Funding/Contracting body 2:

Funding/Contracting body 3:

SECTION 2: NATURE OF RESEARCH

2.1 **The nature of this project is most appropriately described as research involving:- (more than one may apply):**

–	**behavioural observation**	Y:
–	**self-report questionnaire(s)**	Y: ☑
–	**interview(s)**	Y:
–	**qualitative methodologies (e.g. focus groups)**	Y: ☑
–	**psychological experiments**	Y:
–	**epidemiological studies**	Y:
–	**data linkage studies**	Y:
–	**psychiatric or clinical psychology studies**	Y:
–	**human physiological investigation(s)**	Y:

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– **biomechanical device(s)** ☐ **Y**

– **human tissue** ☐ **Y**

– **human genetic analysis** ☐ **Y**

– **<u>a clinical trial of drug(s) or device(s)</u>** ☑ **Y**

– **Other (please specify in the box below)** ☐ **Y**

Proceed to Section 3.

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SECTION 3: PARTICIPANTS AND RECRUITMENT

3.1 (a) What is the age range of all participants involved in this study?

≥ 18 (Adults)

(b) Are the participants include children (defined by statute for this purpose as anyone under 18) ☐ **Y** ☑ **N**

If you answered NO, give reasons why not.

Post-operative urinary retention might be a relatively rare occurrence in children compared to adults. Also, age-related differences in etiology, risk factors, and management of postoperative urinary retention might differ between adults and children due to anatomical, physiological, and developmental variations.

3.2 Are the participants:- (more than one may apply)

- **in a teacher–student relationship with the researchers or their associates?** ☐ **Y**
- **in an employer–employee relationship with the researchers or their associates?** ☐ **Y**
- **in any other dependent relationship with the researchers or their associates?** ☐ **Y**
- **prisoners?** ☐ **Y**
- **refugees?** ☐ **Y**
- **members of the security services?** ☐

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–	**mentally ill?**	**Y** ☐
–	**intellectually impaired?**	**Y** ☐
–	**unconscious or critically ill patients?**	**Y** ☐
–	**in a doctor–patient relationship or a health giver–receiver relationship with the researchers or their associates?**	**Y** ☑

If you answered YES to any of the above, provide details.

3.3 (a) What is the sample size for the study? Comment on how this sample size will allow the aims of the study to be achieved.

The target sample will be about 1084 patients. The sample size was calculated by a power analysis based on the expected effect size and significance level. This allows for a reduction of bias and provides a precise relationship between an intervention and the outcome.

3.4 Will participants receive any reimbursement **N** ☑ **Y** ☐

If you answered YES, what is the amount or nature of the reward and the justification for this?

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Proceed to section 4

SECTION 4: PRIVACY

4.1 Is there a requirement for the researchers to identify, collect, use, or disclose information of a personal nature *(either identifiable or potentially identifiable)* about individuals without their consent?

☑	
N	**Y**

If you answered YES, state what information will be sought and how many records will be accessed.

IF YOU ANSWERED NO, YOU DO NOT NEED TO COMPLETE ANY MORE OF SECTION 4. GO TO SECTION 5

Please provide details

Proceed to Section 5.

SECTION 5: COLLECTION OF DATA

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5.1 Will any part of the study involve <u>recordings</u> using audio tape, film/video, or other electronic medium ? ☑ **N** ☐ **Y**

If you answered YES, what is the medium and how it will be used?

5.2 Does your research involve the <u>secretive</u> use of photographs, tape-recordings, or any other form of record-taking? ☑ **N** ☐ **Y**

If you answered YES, provide details and a justification for the secrecy.

5.3 (a) How will the results of the study be disseminated (e.g. via publication in journals and presentations in scientific meetings)?

The results will be published in a journal, and shared in conferences.

5.4 How will the confidentiality of the data, including the identity of participants, be ensured during collection and dissemination?

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- Participants will be asked some questions after the surgery, no collection of their name or address will be done.
- Participants' file number will not be shared with the data or the research results.

5.5 (a) What is the proposed storage location of, and access to, materials collected during the study (including files, audiotapes, questionnaires, videotapes, photographs)?

Please cross (X) the appropriate box:

	Principal investigator's Office	**Room No.**		**Building**	
	Faculty / Departmental Office	**Room No.**		**Building**	
X	**Other** (Please provide details below)				

A shared Google drive by authors

(b) On completion of the study, where will the materials that were collected during the study (including files, audiotapes, questionnaires, videotapes, photographs) be stored?

Please cross (X) the appropriate box:

	Principal Investigator's Office	**Room No.**		**Building**	
	Faculty / Departmental Office	**Room No.**		**Building**	
X	**Other** (Please provide details below)				

A shared Google drive by authors

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SECTION 6: ASSESSMENT OF RISKS

6.1 Indicate if the participants might experience any of the following:

Risk of physical harm (e.g., falling, muscle pain)

Y ☐

Physical discomfort (e.g., tiredness, weakness, nausea)

Y ☐

Risk of psychological or emotional harm (e.g., trauma)

Y ☐

Psychological or emotional discomfort (e.g., anxiety, stress, loss of confidence, regret for disclosing personal information)

Y ☐

Legal repercussions for participating in the study (e.g., possibility of being sued, charged with criminal activity)

Y ☐

6.2 POTENTIAL RISK TO PARTICIPANTS AND RISK MANAGEMENT PROCEDURES

Identify, as far as possible, all potential risks to participants (e.g. physical, psychological, social, legal or economic), associated with the proposed research. Please explain what risk management procedures will be put in place.

- No potential risks.
- Any patient who is expected to develop drug-related complications will be excluded from the study.

6.3 ARE THERE ANY SPECIFIC RISKS TO RESEARCHERS THAT ARE GREATER THAN THOSE ENCOUNTERED IN NORMAL DAY TO DAY LIFE?

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☐ YES ☑ NO *(If YES, please describe.)*

End of the application