

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

A comparative study on the effect of different doses of dexamethasone on blood glucose concentration in patients undergoing elective abdominal surgery

Protocol summary

Study aim

Determination of the effect of different dexamethasone doses on blood glucose concentrations in patients under elective abdominal surgery

Design

This randomized double blind clinical trial was performed on patients with elective abdominal surgery referred to Rasoul-e-Akram Hospital. The number of individuals was 96 randomly selected and randomly divided into three groups of intervention, first intervention and control.

Settings and conduct

A total of 96 patients who had undergone abdominal surgery who referred to Rasoul-e-Akram Hospital were randomly divided into three groups (two intervention and one control group). Also, the grouping of the patients and the type of drug used for the subjects involved in the study are blinded. As the patient, researcher and data analyst will be blind. (double blinded)

Participants/Inclusion and exclusion criteria

Including criteria: Patients undergoing abdominal surgery, aged 18-65 years. Excluding criteria: Cardiovascular, pulmonary, renal, hepatic, diabetic patients - Dissatisfaction to enter the study - Recent history of steroid use - History of allergy to any of the drugs used in the study.

Intervention groups

In a group, 4 mg intravenous dexamethasone is injected at the beginning of the surgery, and in the second group, 8 mg dexamethasone and the third group, placebo (normal saline) are injected.

Main outcome variables

After surgery, blood glucose levels were measured and recorded by the nurse at 6 hours and 24 hours after administration of dexamethasone or placebo. After recording the data, the results of the three groups are compared and analyzed statistically.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120814010599N13**

Registration date: **2017-12-21, 1396/09/30**

Registration timing: **prospective**

Last update: **2017-12-21, 1396/09/30**

Update count: **0**

Registration date

2017-12-21, 1396/09/30

Registrant information

Name

Poupak Rahimzadeh

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6650 9059

Email address

p-rahimzadeh@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-22, 1396/10/01

Expected recruitment end date

2018-04-21, 1397/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study on the effect of different doses of dexamethasone on blood glucose concentration in patients undergoing elective abdominal surgery

Public title

Effect of dexamethasone on blood glucose concentration

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

All people who are candidates for abdominal surgery

Exclusion criteria:

cardiovascular patients Recent history of steroid use
History of allergy to any of the drugs used in the study.
pulmonary patients renal patients hepatic patients DM patients

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **96**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients who are included in the study are divided into three groups based on the randomization block using a random number table.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient does not know which medicine he receives.
The nurse is aware; the researcher like the patient does not know which patient is in what group and which method he receives. The counselor, as well as the nurse, knows which patient, which method Receives.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Science

Street address

Iran University of Medical Sciences,next to Milad Tower,Hemmat Highway,Tehran

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2015-12-09, 1394/09/18

Ethics committee reference number

ir.iums.rec.1394.8821215176

Health conditions studied

1

Description of health condition studied

Hyperglycemia due to steroid

ICD-10 code

T38.0X5A

ICD-10 code description

Adverse effect of glucocorticoids

Primary outcomes

1

Description

blood glucose levels

Timepoint

After surgery, at 6 hours and 24 hours after administration of dexamethasone or placebo.

Method of measurement

Blood glucose is measured using a glucometer

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1 : . Before the intervention, blood glucose and other basic indicators are checked. 32 patients In a group ,4 mg intravenous dexamethasone is injected at the beginning of the surgery, The drugs are prepared by the operating room pharmacy in 3 ml syringes labeled as patient name. . After surgery, blood glucose levels were measured and recorded by the nurse at 6 hours and 24 hours after administration of dexamethasone or placebo.

Category

Prevention

2

Description

Intervention group 2 : . Before the intervention, blood glucose and other basic indicators are checked and. 32 patients in the second group, 8 mg dexamethasone are injected. The drugs are prepared by the operating room pharmacy in 3 ml syringes labeled as patient name. After surgery, blood glucose levels were measured and recorded by the nurse at 6 hours and 24 hours after administration of dexamethasone or placebo.

Category

Prevention

3**Description**

Control group: Before the intervention, blood glucose and other basic indicators are checked. 64 patients in the third group, placebo (normal saline) are injected. . The drugs are prepared by the operating room pharmacy in 3 ml syringes labeled as patient name.. After surgery, blood glucose levels were measured and recorded by the nurse at 6 hours and 24 hours after administration of dexamethasone or placebo.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Rasool-E-Akram hospital

Full name of responsible person

Dr. Mehrdad KHodabandeh

Street address

Rasool-e-Akram hospital, Niayesh street, Satarkhan street

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khodabandeh.mehrdad@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Ali Javad Mosavi

Street address

Iran University of Medical Sciences , next to Milad Tower, Hemmat Highway

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Tehran

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1449614535

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khodabandeh.mehrdad@gmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Iran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Poupak Rahimzadeh

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Fifth floor, Central staff, Iran University of Medical Sciences, Hemmat Highway

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Poupak Rahimzadeh

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Latest degree

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Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Data file of people not identifiable, protocol of doing the study, How to analyze data, informed consent from individuals, A report from a clinical study and its outcome

When the data will become available and for how long

Start the access period : 1 month after printing results

To whom data/document is available

Researchers working in academic centers

Under which criteria data/document could be used

Specific conditions for use by individuals will not be considered

From where data/document is obtainable

Contact Dr. Mehrdad Khodabandeh by email
khadabandeh.mehrdad@gmail.com

What processes are involved for a request to access data/document

By sending an email and requesting the request, after a day, the information will be sent to the person

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Poupak Rahimzadeh

Position

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Latest degree

Subspecialist

Other areas of specialty/work

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