Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

A Comparative Study on the Effect of Azan Voice and Water Voice on Depth of Anesthesia and Hemodynamic and Plasma and Blood Glucose Cortisol Levels in Patients Submitted to Laparoscopic Cholecystectomy

Protocol summary

Study aim

Comparison of the Effect of Azan Voice and Water Flow on the Depth of Anesthesia and Hemodynamics of Patients and the Level of Cortisol and Plasma Glucose in Patients During Laparoscopic Cholecystectomy

Design

Randomized double blind clinical trial with control group

Settings and conduct

In this study, 120 samples of patients operating general room of Kashani Hospital in Shahrekord who were candidates for cholecystectomy were selected by simple sampling.They were randomly divided into four groups and matched and operated by a same surgeon.Before induction of anesthesia, all patients are assigned a Bispectral index(BIS) kit and their number and blood pressure and heart rate and the baseline plasma cortisol and blood glucose levels are recorded.For all patients with headphones, the first group of Azan sound, the second group of sound water and the third group no sound, and in the control group, headphones are not installed.After induction of anesthesia, in 5 to 35 minutes, the variables are checked in all groups.After completing surgery in recovery, in addition to hemodynamics, pain and anxiety score and cortisol and blood glucose levels are measured.Patient information is recorded separately in the checklist and analyzed.

Participants/Inclusion and exclusion criteria

All individuals aged 20 to 60 years without disease candidate for laparoscopic cholecystectomy

Intervention groups

The patients were divided into 4 groups: the first group was the Azan sound, the second group was waterless and the fourth group was without sound.

Main outcome variables

Depth of anesthesia, heart rate, blood pressure, plasma cortisol level, blood glucose level, pain score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181030041502N1**
Registration date: **2018-11-12, 1397/08/21**
Registration timing: **retrospective**

Last update: **2018-11-12, 1397/08/21**
Update count: **0**

Registration date

2018-11-12, 1397/08/21

Registrant information

Name

Ebrahim Tavafzade

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-12-21, 1395/10/01

Expected recruitment end date

2017-09-22, 1396/06/31

Actual recruitment start date

2016-12-21, 1395/10/01

Actual recruitment end date

2017-09-22, 1396/06/31

Trial completion date

2017-09-22, 1396/06/31

Scientific title
A Comparative Study on the Effect of Azan Voice and Water Voice on Depth of Anesthesia and Hemodynamic and Plasma and Blood Glucose Cortisol Levels in Patients Submitted to Laparoscopic Cholecystectomy

Public title
A Comparative Study of Voices on Patients under Surgery

Purpose
Other

Inclusion/Exclusion criteria

Inclusion criteria:
Patients aged 20-60 years undergoing laparoscopic cholecystectomy No history of restrictive disease Lack of uncontrolled blood pressure and diabetes and glucose intolerance Don't use opioid or hypnotic drugs Lack of hearing loss Lack of a history of a disease or use of a medication that disturbs the level of normal cortisol levels of plasma and blood glucose BMI<30 Asa class 1,2 Patient satisfaction from participating in the plan

Exclusion criteria:

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **120**
Actual sample size reached: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization using the Random Allocation Software , and in that third party, categorize the groups into A = Azan, B = Water, C = No-Audio Headphones and D = Controller and At the top of the questionnaire, the group is identified with the letter and after entering the patient opens the questionnaire and prepares the patient with the same intervention And the researcher does not know until the completion of sampling what kind of letter is defined by each group.

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients were not aware of which group they were and the researcher did not know which group was in each case and the questionnaire was completed by a third person.

Placebo
Not used

Assignment
Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Shahrekord University of Medical Sciences

Street address
Shahrekord, Kashani Blvd., Headquarters of the University

City
shahrekord

Province
Chahar-Mahal-va-Bakhtiari

Postal code
۸۸۱۵۷۱۳۴۷۱

Approval date
2016-08-28, 1395/06/07

Ethics committee reference number
IR.SKUMS.REC.1395.137

Health conditions studied

1

Description of health condition studied
Patients undergoing laparoscopic cholecystectomy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Depth of Anesthesia

Timepoint
Before induction of anesthesia and immediately after and 5 to 35 minutes after induction and immediately after surgery in recovery and one hour after surgery in recovery

Method of measurement
BIS KIT

2

Description
Blood pressure

Timepoint
Before induction of anesthesia and immediately after and 5 to 35 minutes after induction and immediately after surgery in recovery and one hour after surgery in recovery

Method of measurement
Mercury barometric device

3

Description
Heart rate
Timepoint
Before induction of anesthesia and immediately after and 5 to 35 minutes after induction and immediately after surgery in recovery and one hour after surgery in recovery
Method of measurement
Pulse oximetry

4

Description
Plasma cortisol
Timepoint
Before induction of anesthesia and an hour after surgery in recovery
Method of measurement
Serum test

5

Description
Blood sugar
Timepoint
Before induction of anesthesia and an hour after surgery in recovery
Method of measurement
Serum test

6

Description
Pain score
Timepoint
Immediately after surgery and an hour later in recovery
Method of measurement
Visual Analog Scale

Secondary outcomes

empty

Intervention groups

1

Description
Control group:
Category
Treatment - Surgery

2

Description
Intervention group:
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
kashani hospital
Full name of responsible person
Dr Saeed Aali
Street address
parastar street,kashani hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
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res.med@skums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahre-kord 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
Shahre-kord University of Medical Sciences
Full name of responsible person
Dr Hossein Madineh
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available