Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Are the operating rooms with laminar airflow systems a risk for inadvertent perioperative hypothermia during ureterorenoscopic lithotripsy under spinal anesthesia? A prospective randomized clinical trial.

Protocol summary

Study aim
The aim of our study is to compare that the change of temperature of patients who applied ureterorenoscopic lithotripsy under spinal anesthesia in operating rooms with laminar (LAS-OR) and conventional airflow system (CAS-OR).

Design
Prospective, parallel group and randomized trial

Settings and conduct
A total of 100 volunteers, including Group LAS (n = 50) and Group CAS (n = 50), are planned to be included in the study. The groups of patients will be determined by the random number generation program of the Microsoft Office Exel program (with 100 blocks). The patients will be taken to the operating rooms with laminar airflow system (LAS-OR) or the operating rooms with conventional airflow system (CAS-OR), according to randomization.

Participants/Inclusion and exclusion criteria
Inclusion criteria of study: the patients who are ASA (American Society of Anesthesiologists) I-II risk group, between 18-65 age group, body mass index (BMI) between 18.5-29.9. Exclusion criteria: The patients who treated for hypertension, cardiac arrhythmia, hypothyroid, hyperthyroid and corticoadrenal insufficiency, hypothermia during the preoperative period.

Intervention groups
The patients will be taken to the operating rooms with laminar airflow system (LAS-OR) or the operating rooms with conventional airflow system (CAS-OR), according to randomization.

Main outcome variables
To measure tympanic membrane temperature preoperative and every 15 minutes during ureterorenoscopic lithotripsy.

General information

Reason for update

Acronym
ALARIPHURS

IRCT registration information
IRCT registration number: **IRCT20180324039145N5**
Registration date: **2018-11-02, 1397/08/11**
Registration timing: **prospective**

Last update: **2018-11-02, 1397/08/11**
Update count: **0**

Registration date
2018-11-02, 1397/08/11

Registrant information

Name
Recai Dagli

Name of organization / entity
Ahi Evran University Faculty of Medicine

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Turkey

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-12-01, 1397/09/10

Expected recruitment end date
2019-12-01, 1398/09/10

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Are the operating rooms with laminar airflow systems a risk for inadvertent perioperative hypothermia during ureterorenoscopic lithotripsy under spinal anesthesia? A prospective randomized clinical trial.

Public title

Airflow systems in the operating rooms and the heat loss of patients during surgery.

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:

The patients who will be applied ureterorenoscopic surgery under spinal anesthesia The patients who ASA (American Society of Anesthesiologists) score I-II The patients who in the 18-65 age group The patients who with the body mass index (BMI) between 18.5-29.9

Exclusion criteria:

The patients who treated for hypothyroid or hyperthyroid The patients who treated for corticoadrenal insufficiency The patients who treated for hypertension or arrhythmia The patients who treated for hypothermia during preoperative period.

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

A total of 100 volunteers will be included in this study and divided two groups, laminar airflow systems [Group LAS (n = 50)] and conventional airflow systems [Group CAS (n = 50)]. The random number generation program of the Microsoft Office Exel program will be used to determine the groups of patients (with 100 blocks).

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ahi Evran University Ethics Committee for Clinical Investigations

Street address

No.100, Bagbasi St, Kirsehir

City

Kirsehir

Postal code

40100

Approval date

2018-03-27, 1397/01/07

Ethics committee reference number

2018-06/56

Health conditions studied

1

Description of health condition studied

Inadvertent perioperative hypothermia

ICD-10 code

T88.51

ICD-10 code description

Hypothermia following anesthesia

Primary outcomes

1

Description

to detect the change between the preoperative temperature and the temperature measured each fifteen-minutes during the ureterorenoscopic lithotripsy (ΔT).

Timepoint

every fifteen-minutes during the ureterorenoscopic lithotripsy, until the end of the operation.

Method of measurement

The tympanic membrane temperature of patients will be measured with Braun IRT6520

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients who will undergo ureterorenoscopic lithotripsy under spinal anesthesia, determined according to randomization, will be taken to the operating rooms with laminar airflow (LAS-OR).

Category

Early detection

2

Description
Control group: Patients who will undergo ureterorenoscopic lithotripsy under spinal anesthesia, determined according to randomization, will be taken to the operating rooms with conventional airflow (CAS-OR).
Category
Early detection

Recruitment centers

1

Recruitment center
Name of recruitment center
Department of Anaesthesiology and Reanimation, Ahi Evran University Faculty of Medicine
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Department of Anaesthesiology and Reanimation, Ahi Evran University Faculty of Medicine
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact
Name of organization / entity
Department of Anaesthesiology and Reanimation, Ahi Evran University Faculty of Medicine
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Recai Dagli
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no further information

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available