

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of the efficacy of a new Apnea test method in confirmation of brain death and comparison with the current method

Protocol summary

Study aim

Determining the efficacy of a new Apnea test method in confirming brain death

Design

Non-randomized crossover clinical trial+

Settings and conduct

The intensive care unit of Al-Zahra teaching hospital 100% oxygen was given to the patient for 10 minutes before the patient was removed from the ventilator. The patient is then removed from the apparatus and oxygenated at 6 liters per minute by a narrow Nellon catheter inserted into the endotracheal tube. Serial arterial blood gas testing allows the blood carbon dioxide to gradually reach 60 mm Hg, or rise to as much as 20 mm Hg. If you do not see any respiratory activity, the apnea test confirms brain death. In the new method, induction hypercapnia is used instead of hyperventilating and then separating the brain death patient from the ventilator, and with a minimum volume of minutes adjustable on the ventilator, increased blood carbon dioxide and instead of repeated arterial blood gas measurements, Expired carbon dioxide calculates blood carbon dioxide levels, and when exhaled carbon dioxide reaches the target, it examines arterial blood gases and compares exhaled carbon dioxide with blood carbon dioxide.

Participants/Inclusion and exclusion criteria

Inclusion: Get written consent from legal relatives of a brain death patient Exclusion: Lack of parental consent to do Apnea test Cases that are not hemodynamically stable.

Intervention groups

Prior to the patient's removal from the ventilated oxygen, he was oxygenated and removed from the device and oxygenated with a Nellon Bark probe into the endotracheal tube. We then perform a serial arterial blood gas test. In the new method, we use induction hypercapnia and examine arterial blood gases when exhaled carbon dioxide reaches the target.

Main outcome variables

Cost of performing repeated arterial blood gas tests, hypoxia, hypotension, bradycardia, tachycardia, pneumothorax, cardiac arrest

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200209046433N1**

Registration date: **2020-03-11, 1398/12/21**

Registration timing: **registered_while_recruiting**

Last update: **2020-03-11, 1398/12/21**

Update count: **0**

Registration date

2020-03-11, 1398/12/21

Registrant information

Name

parviz kashefi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3662 2596

Email address

kashefi@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-04, 1398/11/15

Expected recruitment end date

2020-09-22, 1399/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the efficacy of a new Apnea test method in confirmation of brain death and comparison with the current method

Public title

Evaluation of the efficacy of a new Apnea test method in confirmation of brain death and comparison with the current method

Purpose

Diagnostic

Inclusion/Exclusion criteria**Inclusion criteria:**

Sick of brain death. Get written consent from the patient's legal relatives

Exclusion criteria:

Lack of parental consent to do Apnea test Cases that are not hemodynamically stable.

AgeFrom **12 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **60****Randomization (investigator's opinion)**

Not randomized

Randomization description**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**

Ethics committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jerib Ave.

City

Isfahan

Province

Isfahan

Postal code

8164644193

Approval date

2020-02-01, 1398/11/12

Ethics committee reference number

IR.MUI.MED.REC.1398.561

Health conditions studied**1****Description of health condition studied**

Brain Death

ICD-10 code

G93.82

ICD-10 code description

Brain death

Primary outcomes**1****Description**

Cost of performing repeated arterial blood gas tests

Timepoint

During hospitalization

Method of measurement

Induction of Hypercapnia

2**Description**

Hypoxia

Timepoint

During hospitalization

Method of measurement

Pulse Oximeter

3**Description**

Hypotension

Timepoint

During hospitalization

Method of measurement

Mercury barometer

4**Description**

Bradycardia and Tachycardia

Timepoint

During hospitalization

Method of measurement

Electrocardiogram

5**Description**

Pneumothorax

Timepoint

During hospitalization

Method of measurement

Examination

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: The intensive care unit of Al-Zahra teaching hospital 100% oxygen was given to the patient for 10 minutes before the patient was removed from the ventilator. The patient is then removed from the apparatus and oxygenated at 6 liters per minute by a narrow Nellon catheter inserted into the endotracheal tube. Serial arterial blood gas testing allows the blood carbon dioxide to gradually reach 60 mm Hg, or rise to as much as 20 mm Hg. If you do not see any respiratory activity, the apnea test confirms brain death. In the new method, induction hypercapnia is used instead of hyperventilating and then separating the brain death patient from the ventilator, and with a minimum volume of minutes adjustable on the ventilator, increased blood carbon dioxide and instead of repeated arterial blood gas measurements, Expired carbon dioxide calculates blood carbon dioxide levels, and when exhaled carbon dioxide reaches the target, it examines arterial blood gases and compares exhaled carbon dioxide with blood carbon dioxide.

Category

Early detection

2**Description**

Control group: In this group, only the classic apnea test is performed.

Category

Diagnosis

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

Al-Zahra Hospital

Full name of responsible person

Parviz Kashefi

Street address

Al-Zahra Hospital, Sofah Boulevard.

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3668 0048

Email

kashefi@med.mui.ac.ir

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

Esfahan University of Medical Sciences

Full name of responsible person

Ziba Faraj Zadagan

Street address

Isfahan University of Medical Sciences, Hezar Jerib Ave.

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3668 0048

Email

dean@med.mui.ac.ir

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

Yes

Title of funding source

Esfahan 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**

Esfahan University of Medical Sciences

Full name of responsible person

Parviz Kashefi

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Medical Education

Street address

N6,vatan lane,mir st Isfahan

City

Isfahan
Province
Isfahan
Postal code
81746-73461
Phone
+98 31 3662 2596
Fax
Email
Kashefi@med.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Parviz Kashefi
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Medical Education
Street address
N6,vatan lane,mir st Isfahan
City
Isfahan
Province
Isfahan
Postal code
81746-73461
Phone
+98 31 3662 2596
Fax
Email
Kashefi@med.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Parviz Kashefi
Position
Professor

Latest degree
Specialist
Other areas of specialty/work
Medical Education
Street address
N6,vatan lane,mir st Isfahan
City
Isfahan
Province
Isfahan
Postal code
81746-73461
Phone
+98 31 3662 2596
Fax
Email
Kashefi@med.mui.ac.ir

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

Information can be shared two years after release.

When the data will become available and for how long

Information can be shared two years after release.

To whom data/document is available

Doctors and nurses

Under which criteria data/document could be used

Compare this method with another method

From where data/document is obtainable

Send kashefi@med.mui.ac.ir an email

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

Send kashefi@med.mui.ac.ir an email

Comments