Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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.
Age
From **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
Isfehan
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
Isfehan
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
Isfehan
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
Isfehan
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
Isfehan
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
Isfehan
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