Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Oct 2021

Effects of Taurine Powder Supplementation on Inflammatory Markers and Clinical Outcomes in Traumatic Brain Injury Patients Admitted to the Intensive Care Unit

Protocol summary

Study aim

Determination of the effects of supplementation of Taurine powder on inflammatory markers and clinical implications in patients with traumatic brain injury admitted to the intensive care unit

Design

This study is a clinical trial randomized, double blind and parallel, will be carried out on 44 patients with traumatic brain injury,who are eligible for inclusion criteria and admitted to the intensive care unit of Golestan Hospital in Ahvaz. Patients are randomly divided into two groups.

Settings and conduct

this study is a double-blind clinical trial with the aim of evaluating the effect of taurine powder supplementation on inflammatory markers and clinical outcomes in traumatic brain injury patients admitted to intensive care unit at Golestan Hospital, Ahvaz. Neither patients nor the investigator are aware of the fact of receiving or not receiving Taurin, and the gavage of patients is prepared by a third person. Patients at the beginning and at the end of the study are taking 10 ml of venous blood to determine serum levels of IL-6, IL-10, TNF-a and hs-CRP.

Participants/Inclusion and exclusion criteria

At least 18 years old, Patients with traumatic brain injury with GCS = 6-12, receiving entral nutrition. The patient should not be pregnant or breastfeeding, lack of liver or kidney disorders, The patient has not received anti-inflammatory drugs or corticosteroids before entering the study. lack of congenital amino acid disorder. More than 60% of energy and protein requirements are calculated during the first week by enteral nutrition.

Intervention groups

Intervention: Standard Gavage powder for Karen pharma and taurine powder with a dose of 30 mg /kg body weight divided in two doses for 14 days Control : Standard Gavage powder for Karen pharma for 14 days

Main outcome variables

IL-6, IL-10, TNF-a, hs-CRP, weight,disease severity, malnutrition,Time of connecting to the ventilator

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180514039657N1**
Registration date: **2018-06-22, 1397/04/01**
Registration timing: **registered_while_recruiting**

Last update: **2018-06-22, 1397/04/01**
Update count: **0**

Registration date

2018-06-22, 1397/04/01

Registrant information

Name

mahsa vahdat

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 61 3373 8253

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-10, 1397/03/20

Expected recruitment end date

2019-01-10, 1397/10/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Taurine Powder Supplementation on Inflammatory Markers and Clinical Outcomes in Traumatic Brain Injury Patients Admitted to the Intensive Care Unit

Public title

effects of taurine in traumatic brain injury

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

At least 18 years old GCS=6-12 traumatic brain injury patients receive entral nutrition

Exclusion criteria:

Taking anti-inflammatory drugs or corticosteroids before entering the study Patients with liver or kidney disorders Pregnant or lactating women Patients with Congenital Amino Acid Metabolism Disorder Failure to provide more than 60% of the energy and protein requirement calculated through entral nutrition in the first week

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Assignment of patients to each groups is done by random block method using block of size 6.In order to ensure that the selection bias does not occur, the allocation method is used to allocate a unique code to each patient.

Blinding (investigator's opinion)

Double blinded

Blinding description

the type of blinding in our study is double-blind. Taurine powder is dissolved by an individual except the researcher in the gavage solution and is coded as A and B, so that the investigator will not be informed of the patient's receipt or not of Taurine. Patients are randomly allocated to each group A and B.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz University of Medical Sciences

Street address

Vice Chancellor for Research and Technology, Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd, Ahvaz

City

ahvaz

Province

Khouzestan

Postal code

61357-15794

Approval date

2018-01-27, 1396/11/07

Ethics committee reference number

IR.AJUMS.REC.1396.919

Health conditions studied

1

Description of health condition studied

traumatic brain injury

ICD-10 code

S06.2

ICD-10 code description

Diffuse traumatic brain injury

Primary outcomes

1

Description

high sensitive C-Reactive Protein

Timepoint

The beginning and end of the study

Method of measurement

ELISA

2

Description

Tumor Necrosis Factor-alpha

Timepoint

The beginning and end of the study

Method of measurement

ELISA

3

Description

Interleukin-6

Timepoint
The beginning and end of the study
Method of measurement
ELISA

4

Description
Interleukin-10
Timepoint
The beginning and end of the study
Method of measurement
ELISA

5

Description
weight
Timepoint
The beginning and end of the study
Method of measurement
Patient bedside scale

6

Description
Clinical outcome measurement
Timepoint
day 1,7,14
Method of measurement
Sequential Organ Failure Assessment(SOFA) score

7

Description
disease severity
Timepoint
day 1,14
Method of measurement
APACHEII score

Secondary outcomes

1

Description
30-day mortality
Timepoint
day 30
Method of measurement
Contact with patient's family

2

Description
length of stay to ICU
Timepoint
daily
Method of measurement
observation

3

Description
malnutrition
Timepoint
The beginning and end of the study
Method of measurement
subjective global assessment

4

Description
Dependence on ventilator
Timepoint
daily
Method of measurement
Counting the number of ventilator attachment days

Intervention groups

1

Description
Intervention group: standard entrameal of karen pharma with taurine powder with a dose 30 mg/kg in two divided doses per day for 14 days
Category
Treatment - Drugs

2

Description
Control group: standard entrameal of karen pharma for 14 days
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ahvaz Golestan Hospital
Full name of responsible person
mahsa vahdat
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Ahvaz Golestan hospital, Golestan Blvd, Ahvaz
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Ahvaz 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
Ahvaz University of Medical Sciences

Full name of responsible person
Mahsa Vahdat

Position
Msc Student

Latest degree
Bachelor

Other areas of specialty/work
Nutrition

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Title and more details about the data/document

If the decision is to publicate the data, after the unidentified individuals all data will be publicated.

When the data will become available and for how long

The access period will be 6 months after the publication of the results.

To whom data/document is available

Researchers working in academic and industrial institutions can apply to get data.

Under which criteria data/document could be used

To cite. Referring to reference or researcher's permission

From where data/document is obtainable

Mahsa Vahdat. Faculty of Paramedicine, jundishapur University of Medical Sciences, golestan Blvd, Ahvaz. vahdat.m@ajums.ac.ir

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

Access to articles related to this research Send email to the responsible author

Comments