

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Investigating the Effect of Royal jelly on the Level of Consciousness of Head Trauma Patients Hospitalized in the Intensive Care Unit

Protocol summary

Study aim

Investigating the Effect of Royal jelly on the Level of Consciousness of Head Trauma Patients Hospitalized in the Intensive Care Unit

Design

Randomized clinical trial with control group, With parallel groups, Double blinded, Phase 3 on 30 patients in each group, Randomization using the random blocking method.

Settings and conduct

The study will be done at the Intensive Care Unit of Musavi Hospital in Zanjan. Patients are blind to the type of intervention and the research assistant who will control the level of consciousness as a result will be blind to the random allocation and type of intervention group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: To have an age range between 18 and 65 years old; To be Admitted with a diagnosis of traumatic brain injury; To have 5 to 13 level of consciousness based on Glasgow coma scale; Not to be sensitive to bee product; Not to be pregnant; To be admitted to the ICU for more than 48 hours; Not to be drugs addict; Not to have a severe trauma to other organs; Not to receive sedative as a continuous infusion; To be started Feeding through the mouth or gavage; Not to have severe mental illnesses; To have hemodynamic stability. Exclusion criteria: Discharge or death of the patient before day 14 in each group; Lack of willingness to continue participating in the study by the patient's legal guardian at any stage of the study; Changes in the patient's condition to prevent the possibility of intervention, such as sending the patient to another hospital.

Intervention groups

In the intervention group 3000 mg of Royal jelly solution dissolved in 30 ml of water will be given to the patients twice a day for 14 days. The control group will only receive routine care and the level of consciousness will be measured by Glasgow coma scale (GCS) and FOUR

scale daily for 14 days in each group.

Main outcome variables

Level of consciousness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150805023520N4**

Registration date: **2020-06-29, 1399/04/09**

Registration timing: **prospective**

Last update: **2020-06-29, 1399/04/09**

Update count: **0**

Registration date

2020-06-29, 1399/04/09

Registrant information

Name

Nasrin Hanifi

Name of organization / entity

Zanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 24 3377 2513

Email address

nasrinhanifi@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-30, 1399/04/10

Expected recruitment end date

2020-10-31, 1399/08/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the Effect of Royal jelly on the Level of Consciousness of Head Trauma Patients Hospitalized in the Intensive Care Unit

Public title

Effect of Royal jelly on the Level of Consciousness

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

To have an age range between 18 and 65 years old To be Admitted with a diagnosis of traumatic brain injury To have 5 to 13 level of consciousness based on Glasgow coma scale Not to be sensitive to Bee product Not to be pregnant To be admitted to the ICU for more than 48 hours Not to be drugs addict Not to have a severe trauma to other organs Not to receive sedative as a continuous infusion To be started Feeding through the mouth or gavage Not to have severe mental illnesses To have hemodynamic stability

Exclusion criteria:

discharge or death of the patient before day 14 in each group Lack of willingness to continue participating in the study by the patient's legal guardian at any stage of the study Changes in the patient's condition to prevent the possibility of intervention, such as sending the patient to another hospital, cardiac arrest

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Sixty patients will be selected as available and then randomly assigned to two intervention groups (Royal jelly) and the control group using the random blocking method. As such, 6 blocks of 4 are provided as follows.1) AAB2 2) ABAB 3) ABBA 4) BBAA 5) BABA 6) BAAB. Block selection is based on the random number table. Group A will receive Royal jelly and group B will be the control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Given that the patients have a low level of consciousness, they are blind to the type of intervention. Also, the research assistant who will control the level of

the patients' awareness as a result will be blind to the random allocation and type of intervention group.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Zanjan University of Medical Science

Street address

Zanjan University of Medical Science, Azadi Square

City

Zanjan

Province

Zanjan

Postal code

4515613191

Approval date

2020-04-28, 1399/02/09

Ethics committee reference number

IR.ZUMS.REC.1399.058

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

Traumatic Brain Injury

ICD-10 code

S06

ICD-10 code description

Intracranial injury

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

Level of Consciousness

Timepoint

after intervention, The second to fourteenth day of hospitalization

Method of measurement

GCS and FOUR score

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients will receive 3000 mg of fresh Royal jelly solution dissolved in 30 ml of water through the mouth or gavage, twice a day for 14 days. The gel used is Royal Jelly, which is a Bee product that is completely natural and has an official license. Royal Jelly belongs to Zanjan Beekeepers Company. The level of consciousness will be measured by Glasgow coma scale (GCS) and Full Outline of Unresponsiveness scale (FOUR) daily for 14 days.

Category

Rehabilitation

2

Description

Control group: Patients will only receive routine care and the level of consciousness will be measured by Glasgow coma scale (GCS) and Full Outline of Unresponsiveness scale (FOUR) daily for 14 days.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Mousavi Hospital

Full name of responsible person

Zahra Shafeie

Street address

Mousavi Hospital, Road Gavazng

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Alireza Shogli

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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

Zanjan 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

Zanjan University of Medical Sciences

Full name of responsible person

Nasrin Hanifi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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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

no more 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

Not applicable

Data Dictionary

Not applicable

Person responsible for updating data**Contact****Name of organization / entity**

Zanjan University of Medical Sciences

Full name of responsible person

Nasrin Hanifi

Position

Associate professor

Latest degree

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