Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

comparison of the effectiveness of acetaminophen and acetaminophen plus caffeine in treatment of electroconvulsive therapy induced headache in psychiatric patients.

Protocol summary

Study aim
The aim of study is to compare acetaminophen and acetaminophen plus caffeine in treatment of electroconvulsive therapy induced headache.

Design
Randomized, single blinded, parallel clinical trial

Settings and conduct
Data is collected from inpatients and outpatients of Roozbeh hospital of psychiatric diseases in Tehran city. Investigator is blinded as pharmacy staff who put drugs in two groups of packets named A and B while investigator is unaware which packet contains which drug.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age 18 to 65 years old; candidate for electroconvulsive therapy; complain of headache after electroconvulsive therapy session; voluntary agreement to participate in study according to informed consent. Exclusion criteria: intellectual disability; pregnancy or breast feeding; gastrointestinal ulcer; renal or hepatic injuries

Intervention groups
Acetaminophen group: The investigator interviews with the patient who received electroconvulsive therapy about headache intensity, after recovery. Acetaminophen is administered to patient. Investigator interviews with the patient 30 minutes, 1 hour and 2 hours after drug administration about headache intensity. Acetaminophen plus caffeine group: The investigator interviews with the patient who received electroconvulsive therapy, after recovery about headache intensity. Acetaminophen caffeine is administered to patient. Investigator interviews with the patient 30 minutes, 1 hour and 2 hours after drug administration about headache intensity.

Main outcome variables
Headache intensity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170207032435N3**
Registration date: **2018-07-23, 1397/05/01**
Registration timing: **registered_while_recruiting**

Last update: **2018-07-23, 1397/05/01**
Update count: **0**

Registration date
2018-07-23, 1397/05/01

Registrant information

Name
Mahboube Bonyadi

Name of organization / entity
Tehran University of Medical Scienses

Country
Iran (Islamic Republic of)

Phone
+98 21 64120

Email address
m72bonyadi@gmail.com

Recruitment status
Recruitment complete

Funding source
pharmacy faculty, Tehran university of medical sciences, thesis fund

Expected recruitment start date
2017-06-21, 1396/03/31

Expected recruitment end date
2018-09-21, 1397/06/30

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison of the effectiveness of acetaminophen and acetaminophen plus caffeine in treatment of electroconvulsive therapy induced headache in psychiatric patients.

Public title

Acetaminophen plus caffeine in electroconvulsive therapy induced headache

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age: 18 to 65 years old Patients who have been candidate for electroconvulsive therapy by a psychiatrist Patients who answer yes to the question "Do you have headache?" asked by investigator after the therapeutic session Signing the voluntary informed consent by patient or his legal guardian

Exclusion criteria:

Intellectual disability Pregnancy or breast feeding History of allergic reaction to acetaminophen or caffeine Active gastrointestinal ulcer Active renal or hepatic disease, renal or hepatic failure History of cardiovascular disease, history of hypertension

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Investigator

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

we used block randomization by means of online tool on sealedenvelope.com. we made a sequence of 18 blocks. Every block consists of 2 A characters and 2 B characters.

Blinding (investigator's opinion)

Single blinded

Blinding description

The investigator is blinded. The pills are located in packets named A and B. Investigator does not know which pill is in the packet.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

research.tums.ac.ir

Street address

Pharmacy faculty, Tehran university of medical sciences, 16 Azar street, Enghelab street, Tehran city, Iran

City

Tehran

Province

Tehran

Postal code

۱۴۱۷۶۱۴۴۱۱

Approval date

2017-08-07, 1396/05/16

Ethics committee reference number

IR.TUMS.PSRC.REC.1396.3099

Health conditions studied

1

Description of health condition studied

Headache

ICD-10 code

G44.1

ICD-10 code description

Vascular headache, not elsewhere classified

Primary outcomes

1

Description

headache intensity

Timepoint

30 mins, 1 hour & 2 hour after ECT therapy session

Method of measurement

Visual analogue scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After electroconvulsive therapy session, the investigator asks patient about headache . If patient confirms that he has headache, investigator will explain the pain scale requesting from patient to determine the degree of headache intensity by a number from 1 to 10. Then acetaminophen is randomly administered to the patient. 30 minutes, one hour and two hours after drug administration, investigator interviews patient again about his headache intensity

due to pain scale.

Category

Treatment - Drugs

2

Description

Intervention group: After electroconvulsive therapy session, the investigator asks patient about headache . If patient confirms that he has headache, investigator will explain the pain scale requesting from patient to determine the degree of headache intensity by a number from 1 to 10. Then acetaminophen caffeine is randomly administered to the patient. 30 minutes, one hour and two hours after drug administration, investigator interviews patient again about his headache intensity due to pain scale.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ruzbeh psychiatry hospital

Full name of responsible person

Padide Ghaeli

Street address

ر Roozbeh hospital, South Karegar street, Hor square, Enghelab street, Tehra, Iran

City

Tehran

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Tehran

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1333715914

Phone

+98 21 5541 9151

Email

M72bonyadi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical sciences

Full name of responsible person

Dr Mohammad reza Rouini

Street address

16 Azar street, Enghelab street, Tehran, Iran

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Email

pharmacy@tums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Padide Ghaeli

Position

clinical pharmacist, professor, full professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Fax

Email

pghaeli63@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Padide Ghaeli

Position

clinical pharmacist, professor, full professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

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Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mahboube Bonyadi

Position

Pharmacy student

Latest degree

A Level or less

Other areas of specialty/work

Medical Pharmacy

Street address

Pharmacy faculty, 16 Azar street, Enghelab street, Tehran, Iran

City

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Province

Tehran

Postal code

۱۴۱۷۶۱۴۴۱۱

Phone

+98 21 6552 1835

Email

M72bonyadi@gmail.com

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

Our data include age and gender of the patients, technical aspects of each therapeutic session (electrical pulse energy and seizure duration) and headache intensity in determined times.

When the data will become available and for how long

From the end of 2019 to 2021.

To whom data/document is available

Indivisuals who need the data in the field of academic and health researches, health care profesionals and interested students.

Under which criteria data/document could be used

To use in medical decision making by health care professionals, researchers in related fields, limited to people who request data by institution email.

From where data/document is obtainable

Email Mahboube Bonyadi: m72bonyadi@gmail.com
Padide Ghaeli: pghaeli63@gmail.com

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

2 to 4 weeks after request delivery

Comments