

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 2026

Comparison the effects of Acetaminophen and Ibuprofen on emotions by recording electrical activity of the brain

Protocol summary

Study aim

1. Comparison the effect of Acetaminophen and Ibuprofen on emotions by using Electroencephalography signals. 2. The negative effects of painkillers on emotional states and people's empathy

Design

Non randomized clinical trial; Phase 1; 54 volunteers

Settings and conduct

This study performs in laboratory of Islamic Azad University of Central Tehran Branch. Three steps performs for all of subjects between three to seven days; thereby, the electroencephalography brain signals obtain without receiving any medication, with receiving acetaminophen and Ibuprofen during music listening. Each participant listen to a three-minute audio music track for each emotion. Before and after listening of music excerpts and electroencephalography recording, each of people fulfill the questionnaires regarding their emotions.

Participants/Inclusion and exclusion criteria

Inclusion criteria include: 1. People over 18 years old without neurological diseases 2. Right-handed people
Inclusion criteria include: 1. Patients participating in other clinical studies 2. Pregnant or lactating women 3. Sensitivity to any of the drug compounds

Intervention groups

The study will be performed on 54 volunteers without a history of any disease in three stages. Thus, in one stage of signal recording from individuals without receiving any medication and 3 to 7 days later, the person will receive 500 mg of acetaminophen tablets and the signal will be recorded again, in the other stage, the same people in a period of 3-7 take 400 mg of ibuprofen tablets daily. Brain signals are received in three states of joy, sadness and neutrality in the three mentioned stages. Our stimulus in this research is an audio music that creates a state of joy and sorrow in people.

Main outcome variables

1. EEG Brain Signal 2. Emotion (happiness - sadness)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190729044367N1**

Registration date: **2020-08-31, 1399/06/10**

Registration timing: **registered_while_recruiting**

Last update: **2020-08-31, 1399/06/10**

Update count: **0**

Registration date

2020-08-31, 1399/06/10

Registrant information

Name

Neda Kaffash

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4401 2937

Email address

neda.kaffash@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-05, 1399/05/15

Expected recruitment end date

2020-11-05, 1399/08/15

Actual recruitment start date

2020-08-05, 1399/05/15

Actual recruitment end date

2020-11-05, 1399/08/15

Trial completion date

2020-11-21, 1399/09/01

Scientific title

Comparison the effects of Acetaminophen and Ibuprofen on emotions by recording electrical activity of the brain

Public title

Comparison the effects of Acetaminophen and Ibuprofen on emotions

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

All participants should be right-handed They have normal hearing sensitivity No reported history of brain diseases like depression or alzheimer. No head trauma, stroke or injury Do not have history of alcohol and smoking (especially a few days before the signal is recorded)

Exclusion criteria:

Pregnancy Breastfeeding Preexisting neurological or psychological disorders Severe liver failure based on Child-Pugh Score Renal failure (Glomerular Filtration Rate (GFR) < 15 mL/min) History of prior anti-psychotic or anti-epileptic use Allergy to oral Acetaminophen and non-steroidal anti-inflammatory drug (NSAID) History of smoking or alcohol abuse

Age

From **18 years** old to **35 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **54**

Actual sample size reached: **54**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University Of Medical Sciences

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Approval date

2020-01-19, 1398/10/29

Ethics committee reference number

IR.IUMS.REC.1398.1085

Health conditions studied

1

Description of health condition studied

Healthy volunteers

ICD-10 code

R45.89

ICD-10 code description

Other symptoms and signs involving emotional state

Primary outcomes

1

Description

Emotional arousal score in questionnaire between 0-5.

Timepoint

Survey the emotional state immediately after the recording for checking the effect of painkiller.

Method of measurement

Asking participants after recording and score the music from 0-5. and observe and analyze brain signals in both happiness and sadness.

Secondary outcomes

empty

Intervention groups

1

Description

In the first stage, participants are given a brain signal for each emotional state (happiness-sadness-neutral) while listening to a three-minute music. Before and after listening to music, each person fills out a questionnaire according to their feelings. In the second stage, the signal is recorded by receiving acetaminophen (500) mg of Rouz Darou Pharmaceutical Company while listening to the mentioned music. Before and after listening to music, each person fills out the questionnaire according to their feelings. In the third stage, the signal is recorded by receiving ibuprofen (400 mg) from Dana Pharmaceutical Company while listening to the music. . Before and after listening to music, each person fills out a questionnaire according to their feelings.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Firoozgar Hospital

Full name of responsible person

Dr.Maryam Farasatinasab

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Behafarin St, KarimKhanZand St, ValiAsr St, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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

No

Title of funding source

None

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

Islamic Azad University

Full name of responsible person

Neda Kaffash

Position

Master

Latest degree

Master

Other areas of specialty/work

Medical Education

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

Assistant Professor of Clinical Pharmacy

Latest degree

Specialist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Yes - There is 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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

No - There is not a plan to make this available

Title and more details about the data/document

The results of the document is shared but the data can't be shared.

When the data will become available and for how long

The results will be shared after publication.

To whom data/document is available

The data is secret. I can't be allowed to share it.

Under which criteria data/document could be used

they can just analyze mathematically.

From where data/document is obtainable

Neda Kaffash- Maryam Farasatinasab/ Firoozgar Hospital

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

this data is secret. I can't share it

Comments