Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
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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 comittee 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
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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

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Position
Assistant Professor of Clinical Pharmacy

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Specialist

Other areas of specialty/work
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Latest degree

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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