

# 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

**Street address**

Behafarin St, KarimKhanZand St, ValiAsr St, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

4871115937

**Phone**

+98 21 8214 1000

**Email**

neda.kaffash@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Neda Kaffash

**Street address**

Science and Research Branch, Daneshgah Blvd,  
Simon Bulivar Blvd

**City**

Tehran

**Province**

Tehran

**Postal code**

۱۴۷۷۸۹۳۸۵۵

**Phone**

+98 21 4486 5179

**Email**

neda.kaffash@yahoo.com

**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

**Street address**

No. 48, Golestan8, AbazarBlvd, Sadeghie Sq.

**City**

Tehran

**Province**

Tehran

**Postal code**

1471773161

**Phone**

+98 21 4401 2937

**Email**

neda.kaffash@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Maryam Farasatinasab

**Position**

Assistant Professor of Clinical Pharmacy

**Latest degree**

Specialist

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

, School of Pharmacy-International Campus. Kazem  
Besarati St. Kabiri Tameh Ave. Shahid Hemmat Expy

**City**

Tehran

**Province**

Tehran

**Postal code**

1471773161

**Phone**

+98 21 4401 2937

**Email**

maryfarasati@gmail.com

## Person responsible for updating data

### 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 Engineering

**Street address**

No.48, goldasht Ave, abazar Blvd, sadeghie Sq

**City**

tehran

**Province**

Tehran

**Postal code**

1471773161

**Phone**

+98 21 4401 2937

**Email**

neda.kaffash@yahoo.com

## 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**