

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The comparison of the efficacy of stress inoculation training (SIT) with pharmacotherapy in the management of chronic tension headache

Protocol summary

Summary

This study aims to compare the efficacy of two following approaches in the treatment of tension headache as one of the most common headache types; Stress Inoculation Training (SIT) and pharmacotherapy. From those patients who referred to neurology Clinic of Alavi Hospital (Ardabil City) and physicians offices during June and July of 2003 complaining chronic headache, 30 patients were randomly selected and divided into three groups; two intervention groups and one control group. The patients in the first group underwent pharmacotherapy (with Amitriptylline 60mg at night for 6 months) and the second group received SIT intervention (in the three phases as noted in the SIT protocol). Third group received no intervention (control group). Headache indices (frequency, severity, and duration) were evaluated for all subjects in three phases before treatment, shortly after treatment and one month later using Headache Daily questionnaire.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138810022913N1**

Registration date: **2010-04-24, 1389/02/04**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-04-24, 1389/02/04

Registrant information

Name

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Name of organization / entity

Ardabil University of Medical Science

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Isfahan Univeristy

Expected recruitment start date

2003-08-12, 1382/05/21

Expected recruitment end date

2003-11-12, 1382/08/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of the efficacy of stress inoculation training (SIT) with pharmacotherapy in the management of chronic tension headache

Public title

The comparison of the efficacy of stress inoculation training (SIT) with pharmacotherapy in the management of chronic tension headache

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: having a chronic pain, no brain damage, and no other psychiatric disorder Exclusion criteria: recent medical prophylaxis for tension headache, recent psychotherapy, recent pregnancy, migraine headache longer than one day per month, pain disorders (like Arthritis), mental disorder and finally patients disinclination to for the rest of cooperation

Age
From **20 years** old to **30 years** old
Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Isfahan University

Street address
Hezar Jarib Street

City
Isfahan

Postal code

Approval date
2001-01-28, 1379/11/09

Ethics committee reference number
2452-1735

Health conditions studied

1

Description of health condition studied
Tension headache

ICD-10 code
G44.2

ICD-10 code description
Chronic tension-type headache

Primary outcomes

1

Description
frequency, severity and duration of headache

Timepoint

before treatment, after treatment and 1 month after treatment

Method of measurement
headche daily questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

In the intervention group: Stress Inoculation training

Category
Behavior

2

Description

In the Intervention group: Amitriptyline 60mg at night for six months

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Neurlogy Clinic of Alavi Hospital

Full name of responsible person
Street address

City
Ardabil

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Psychology School of Isfahan University

Full name of responsible person
Ahmad Ahmadi

Street address
Hezar Jarib Street

City
Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Psychology School of Isfahan University

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin*empty***Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding***empty***Person responsible for general inquiries****Contact****Name of organization / entity**

Ardabil University of Medical Sciences

Full name of responsible person

Dr Parviz Molavi

Position

Associate Professor

Other areas of specialty/work**Street address**

Fatemi Hospital

City

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Ardabil University of Medical Sciences

Full name of responsible person

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Web page address**Person responsible for updating data****Contact****Sharing plan****Deidentified Individual Participant Data Set (IPD)***empty***Study Protocol***empty***Statistical Analysis Plan***empty***Informed Consent Form***empty***Clinical Study Report***empty***Analytic Code***empty***Data Dictionary***empty*