Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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Name of organization / entity

Ardabil University of Medical Science

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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 Committe 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
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Other areas of specialty/work
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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