

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

A study on nutritional status of riboflavin and the effect of riboflavin supplementation on disability and quality of life scores in patients with multiple sclerosis

Protocol summary

Summary

This is a randomized double blind control trial on 30 patients with multiple sclerosis (MS) introduced to Khuzestan MS society. The aim of this study is the survey of nutritional status of riboflavin and the effect of riboflavin supplementation on disability and quality of life in patients with MS. Inclusion criteria: 1. The approval of MS disease by MS committee, 2. the age between 18-50 years old, 3. the patient should not decide to change or start disease regulation or symptomatic treatments, 4. using bariatric trice for females in productivity age. Exclusion criteria: 1. gestation, 2. intake other vitamins contemporary with riboflavin, 3. contributing in another trials contemporary, 4. the ages under 18 and upper 50 years old. Bloods will obtain for evaluating riboflavin status, measuring serum homocysteine levels and determining blood group after categorizing patients randomly in two groups (intervention and control). Intervention and control groups will receive 10 milligram per day riboflavin capsule and placebo for 6 months, respectively. Primary outcome is improving nutritional riboflavin status and lowering serum homocysteine levels. Independent sample t-test, logistic regression and nonparametric analysis will use to compare qualitative data.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201102175855N1**

Registration date: **2011-04-11, 1390/01/22**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-04-11, 1390/01/22

Registrant information

Name

Mahshid Naghashpour

Name of organization / entity

ACECR-Khuzestan

Country

Iran (Islamic Republic of)

Phone

+98 61 1333 0023

Email address

naghashpour@acecr.ac.ir

Recruitment status

Recruitment complete

Funding source

Ahvaz Jondishapour University of Medical Sciences/
Khuzestan Jahaddaneshgahi (ACECR-Khuzestan)

Expected recruitment start date

2010-10-18, 1389/07/26

Expected recruitment end date

2011-02-09, 1389/11/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A study on nutritional status of riboflavin and the effect of riboflavin supplementation on disability and quality of life scores in patients with multiple sclerosis

Public title

Riboflavin and multiple sclerosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1. The approval of MS disease by MS committee, 2. the age between 18-50 years old, 3. the patient should not decide to change or start disease regulation or symptomatic treatments, 4. using berberine for females in productivity age. Exclusion criteria: 1. gestation, 2. intake other vitamins contemporary with riboflavin, 3. contributing in another trials contemporary, 4. the ages under 18 and upper 50 years old.

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Single

Other design features

We will obtain 5 ML blood for measuring erythrocyte glutathione reductase activity coefficients in fasting. Also, intervention and control groups will obtain riboflavin supplementation (10 mg) and placebo for 24 weeks. Neither patient nor researcher don't informed about which patient set in which group until complete study. Patients will continue their medications. Patients in two groups will complete MSQOL54 questionnaire in the first, sixth and twelfth weeks of study and physician will measure their EDSS. Also 5 ML blood will be obtained for measuring erythrocyte glutathione reductase activity coefficients in fasting in the twelfth week. The score of MSQOL54 questionnaire alternatives which be answered by patients will change to numbers between 0 to 100 and will categorize as percent. Higher score illustrates the better patient life style independent to health.

Secondary IDs

1

Registry name

nothing

Secondary trial ID

nothing

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ahvaz Jondishapour University of Medical Sciences

Street address

Golestan Avenue, Ahvaz

City

Ahvaz

Postal code

Approval date

2011-02-13, 1389/11/24

Ethics committee reference number

3821/پ/20/8/د

Health conditions studied

1

Description of health condition studied

Multiple sclerosis

ICD-10 code

G-35

ICD-10 code description

Multiple sclerosis

Primary outcomes

1

Description

Homocystein serum levels

Timepoint

6 months

Method of measurement

Biochemical test

2

Description

Erythrocyte glutathione reductase activity coefficients

Timepoint

6 months

Method of measurement

Biochemical test

Secondary outcomes

1

Description

EDSS

Timepoint

6 months

Method of measurement

questionnaire

2

Description

quality of life scores

Timepoint

3 mounts

Method of measurement

MSQOL questionnaire

Intervention groups

1

Description

one 10 mg Riboflavin capsul per day, oral, for 6 mounts

Category

Treatment - Drugs

2

Description

placebo: lactos, one capsul per day, for 6 mounts

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Khuzestam Multiple Sclerosis Society

Full name of responsible person

Dr. Nastaran Majdi nasab

Street address

Khuzestan Multiple Sclerosis Society, Rehabilitation Faculty, Jondishapour University of Medical Sciences, Golestan, Ahvaz

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz Jondishapour University of Medical Sciences

Full name of responsible person

Miss Jaderi

Street address

Golestan Avenue, Ahvaz

City

Ahvaz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahvaz Jondishapour University of Medical Sciences

Proportion provided by this source

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

2

Sponsor

Name of organization / entity

ACECR-Khuzestan

Full name of responsible person

Mahshid Naghashpour

Street address

Health Education Department, Jahaddaneshgahi-Khuzestan, Central Organization, Shahid Chamran University, Golestan, Ahvaz

City

Ahvaz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

ACECR-Khuzestan

Proportion provided by this source

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

Khuzestan Multiple Sclerosis Society Office

Full name of responsible person

Miss Kushki

Position

BS, Khuzestan Multiple Sclerosis Society Office responsible

Other areas of specialty/work

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Ahvaz Jondishapour University of Medical Sciences,
Neurology Department

Full name of responsible person

Dr. Nastaran Majdi nasab

Position

Nurologist

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

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

ACECR-Khouzestan

Full name of responsible person

Mahshid Naghashpour

Position

Ph.D student in nutrition

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Web page address**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