

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Assesment of the effect of supplemental aqueous extracts of *Achillea millefolium* on the symptoms, severity and memory deficits in Rafsanjan Multiple sclerosis patients

Protocol summary

Summary

This study follows a previous study group to examine the possible effects of aqueous extracts of yarrow in patients with MS has been developed. The results of this study may introduce a new herbal supplement to help treat MS patients is beneficial. Inclusion criteria were an age of 16 to 55 years; a diagnosis of multiple sclerosis, according to the revised McDonald criteria; a relapsing–remitting course; one or more documented relapses in the previous year or two or more in the previous 2 years; and a score of 0 to 5.5 on the EDSS. Exclusion criteria were relapse or corticosteroid treatment within 30 days before randomization, active infection, or clinically significant systemic disease. The sample size is 75 people. Intervention is Drug treatment and primary end points are change in EDSS score and defined as the number of confirmed relapses per year.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013121915863N1**

Registration date: **2014-03-12, 1392/12/21**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-03-12, 1392/12/21

Registrant information

Name

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Name of organization / entity

Rafsanjan University of Medical Sciences

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Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Rafsanjan University of Medical Sciences

Expected recruitment start date

2014-02-20, 1392/12/01

Expected recruitment end date

2015-02-20, 1393/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assesment of the effect of supplemental aqueous extracts of *Achillea millefolium* on the symptoms, severity and memory deficits in Rafsanjan Multiple sclerosis patients

Public title

Assesment of the effect of supplemental aqueous extracts of *Achillea millefolium* in Multiple sclerosis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria were an age of 16 to 55 years; a diagnosis of multiple sclerosis, according to the revised McDonald criteria; a relapsing–remitting course; one or more documented relapses in the previous year or two or more in the previous 2 years; and a score of 0 to 5.5 on

the EDSS. exclusion criteria were relapse or corticosteroid treatment within 30 days before randomization, active infection, or clinically significant systemic disease.

Age

From **16 years** old to **55 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Rafsanjan University of Medical Sciences

Street address

Enghlab Square

City

Rafsanjan

Postal code

Approval date

2014-02-02, 1392/11/13

Ethics committee reference number

31/9/3040

Health conditions studied

1

Description of health condition studied

multiple sclerosis

ICD-10 code

G35

ICD-10 code description

Multiple sclerosis

Primary outcomes

1

Description

Disability

Timepoint

Before the experiment, three months after the intervention, and six months after intervention

Method of measurement

Expanded Disability Status Scale

2

Description

relapse rate

Timepoint

Course of treatment

Method of measurement

number of confirmed relapses per year

Secondary outcomes

1

Description

Different aspects of cognitive abilities

Timepoint

Before the experiment, three months and six months after the intervention

Method of measurement

Mini-Mental Status Examination test

2

Description

Functional disability and cognitive

Timepoint

Before the experiment and six months after the intervention

Method of measurement

MULTIPLE SCLEROSIS FUNCTIONAL COMPOSITE test

3

Description

Learn Paired of words

Timepoint

Before the experiment, three months and six months after the intervention

Method of measurement

Paired words test

4

Description

Abstract reasoning and cognitive ability to adapt to environmental challenges

Timepoint

Before the experiment, three months and six months after the intervention

Method of measurement

Wisconsin card sorting test

5

Description

Anxiety

Timepoint

Before the experiment, three months and six months after the intervention

Method of measurement

Spielberger state-trait anxiety inventory

6

Description

Fatigue

Timepoint

Before the experiment, three months and six months after the intervention

Method of measurement

Fatigue Severity Scale test

7

Description

Depression

Timepoint

Before the experiment, three months and six months after the intervention

Method of measurement

Beck Depression Inventory

8

Description

Spasticity

Timepoint

Before the experiment, three months and six months after the intervention

Method of measurement

Ashworth test

9

Description

number of gadolinium-enhancing lesions

Timepoint

Before the experiment and six months after the intervention

Method of measurement

MRI

10

Description

New lesion

Timepoint

Before the experiment and six months after the intervention

Method of measurement

MRI

11

Description

Resolvent

Timepoint

Before the experiment, three months and six months after the intervention

Method of measurement

TOWER OF LONDON TEST

Intervention groups

1

Description

Control group: placebo group (placebo) are used. Daily for six months with a number of food consumed. Dose: 250 Mlylygrm capsules containing starch

Category

Treatment - Drugs

2

Description

Intervention group: a group of extract at a dose of 500 mg capsules to take. Daily for six months with a number of food

Category

Treatment - Drugs

3

Description

Intervention group: a group of extract at a dose of 250 mg capsules to take. Daily for six months with a number of food

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Specialized Clinic Hospital, Ali ibn Abi Talib

Full name of responsible person

Doctor Amir Ahmadi Moghaddam - board certified
Neurology - Assistant Professor

Street address

City

Rafsanjan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Doctor Mohammad Mirzai

Street address

Rafsanjan University of Medical Sciences

City

Rafsanjan

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Rafsanjan University of Medical Sciences
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
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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