Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Assesment of the effect of supplemental aqueous extracts of Achillea milefolium 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

Fatemeh Ayoobi

Name of organization / entity

Rafsanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

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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 milefolium on the symptoms, severity and memory deficits in Rafsanjan Multiple sclerosis patients

Public title

Assesment of the effect of supplemental aqueous extracts of Achillea milefolium 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 tese

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
Rafsanjan University of Medical Sciences
Full name of responsible person
fatemeh Ayoobi
Position
PhD research - Collaboration Pharmacology Physiology Research Center
Other areas of specialty/work
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Person responsible for updating data

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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