

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

Comparing the impact of education based on traditional methods and Planned Behavior Theory on Treatment Adherence in Patients with Multiple Sclerosis Receiving Injectable Immunomodulatory Drugs

Protocol summary

Study aim

Determining the effect of educational intervention on the mean score of 1.behavioral beliefs 2.principled beliefs 3.controlled beliefs about drug adherence to multiple sclerosis inject able immuno-modulatory drugs in the intervention and control groups 4.Determining the effect of educational intervention on the mean score of behavioral intention regarding the promotion of drug adherence to multiple sclerosis inject able immuno-modulatory drugs in the intervention and control groups 5.Determining the effect of educational intervention on the mean score of drug adherence using drug adherence questionnaire in MS patients in the intervention and control groups

Design

Clinical trial with control group, with parallel, randomized groups, on 100 patients. Easy sampling was used for randomization.

Settings and conduct

The patients who referred to the MS clinic of Sina Hospital in Tehran.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Patients with Relapsing remitting Multiple Sclerosis 2. Patients treated with Rebif for at least one to four years 3- Patients who have the ability to read and write. 4. Patients with low drug adherence. 5- Patients who want to receive education. 6- ages of 20 to 50 years 7- Patients living in Tehran Exclusion criteria: 1- Patient's dissatisfaction to continue participating in the study 2 - Absence in face-to-face educational intervention sessions 3- Changes in the patient's treatment plan and not receiving Rebif medicine

Intervention groups

Education based on the theory of planned behavior to promote drug adherence in patients with multiple sclerosis who are treated with Rebif and have low drug adherence.

Main outcome variables

Evaluation of 1. drug adherence 2. behavioral & principled and controlled beliefs 3. behavioral intention 4. performance scores in MS patients treated with Rebif before and after the intervention in the both groups

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210808052109N1**
Registration date: **2021-08-12, 1400/05/21**
Registration timing: **prospective**

Last update: **2021-08-12, 1400/05/21**

Update count: **0**

Registration date

2021-08-12, 1400/05/21

Registrant information

Name

Sara Hamtaei Ghashti

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-06, 1400/06/15

Expected recruitment end date

2021-12-06, 1400/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the impact of education based on traditional methods and Planned Behavior Theory on Treatment Adherence in Patients with Multiple Sclerosis Receiving Injectable Immunomodulatory Drugs

Public title

Investigating the effect of education on Multiple Sclerosis patients' drug adherence

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Relapsing Remitting Multiple Sclerosis Patients Be treated with interferon beta-1a(Rebif) at least one to four years

Exclusion criteria:

Patient dissatisfaction to continue participating in the study

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling is easy and patients will be selected based on inclusion criteria. The selected patients will then be divided into two equal groups using block randomization method. The size of the blocks is four and they will be selected from six four-block blocks by random selection by placing samples and will be assigned to two groups.

Blinding (investigator's opinion)

Not 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 Arak University of Medical Sciences

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Alamolhoda Avenue -Shahid Shirodi Avenue - Arak

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Province

Markazi

Postal code

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Approval date

2021-08-01, 1400/05/10

Ethics committee reference number

IR.ARAKMU.REC.1400.082

Health conditions studied**1****Description of health condition studied**

Multiple Sclerosis

ICD-10 code**ICD-10 code description**

Relapsing Remitting Multiple Sclerosis

Primary outcomes**1****Description**

Determining the effect of education based on the theory of planned behavior on the promotion of drug adherence in patients with multiple sclerosis treated with modulatory drugs, beta 1a interferons, which are injected subcutaneously.

Timepoint

Patients are first given a drug compliance questionnaire. Patients are instructed and after three months, a drug compliance questionnaire will be taken from these patients again and the effectiveness of the training will be measured.

Method of measurement

To assess adherence to treatment, two questionnaires are used: 1 - Multiple Sclerosis Treatment Adherence Questionnaire 2- Theoretical questionnaire to assess the impact of the curriculum on the structures of the planned behavior theory

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: In addition to routine training,

training with the theory of planned behavior will be done based on the initial needs assessment. To transfer the training with the theory of planned behavior, a video of how to inject the drug is delivered to the patient at the same time as the routine training. 1- In addition to all the preliminary steps of the drug storage method 2- Preparing the drug for injection 3- Necessary measures before injecting the drug 4- Suitable places in the body for injecting the drug 5- Methods of controlling the unwanted side effects of the drug after injecting it in the mentioned video It is placed at the disposal of patients. In addition, all the above five items are provided to patients in a colored educational pamphlet.

Category

Behavior

2**Description**

Control group: The control group will also receive routine clinical training provided by nurses and clinic staff. Routine training in the MS clinic includes training on how to inject the drug into the appropriate injected tissues, which is a practical training on injecting a dose of the drug into the body. The patient is by the nurse.

Category

Behavior

Recruitment centers**1****Recruitment center****Name of recruitment center**

Comprehensive Multiple Sclerosis Clinic,Sina Hospital

Full name of responsible person

Sara Hamtaei Gashti

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Full name of responsible person

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Arak University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Sara Hamtaei Gashti

Position

Student

Latest degree

Master

Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available