Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Safety and effectiveness of Satinex buccal spray for improving quality of life in multiple sclerosis patients

Protocol summary

Study aim
Evaluating the effectiveness of Satinex buccal spray in improving quality of life in patients suffering multiple sclerosis

Design
Double blinded placebo controlled parallel group trial, randomised, phase 2 clinical trial on 60 patients, block randomisation carried out at "sealedenvelope.com" randomisation website

Settings and conduct
This research is going to be conducted on patients who meet inclusion criteria, they are randomly divided in two groups kept blind(patient and doctor don't know that who gets drug and who doesn't),follow up is done every week via telephone call and 2 times by doctor after the first visit

Participants/Inclusion and exclusion criteria
Inclusion criteria: Informed and written consent of all patients included in the study Patients diagnosed with multiple sclerosis by a specialist Stability of patients disease since one month prior to the study being started Patients Disease Modifying Therapy regimen should remain the same during the study Adults of 18-65 years of age Exclusion criteria: A history of Schizophrenia and other serious mental morbidities (Except depression and anxiety due to MS disease) A history of substance abuse Smoking and generally using cannabis Taking Botulinum shot since 4 months prior to the study starting date a history of serious diseases eg. epilepsy; Myocardial Infarction and heart attack and severe renal and hepatic failure pregnancy and lactation Taking other investigational drugs

Intervention groups
In this research a group of patients are told to take Satinex spray prescribed by their doctor while the placebo group will take a placebo instead (Which is made of ingredients similar to Satinex spray however it does NOT have any Active Pharmaceutical Ingredient in it)

Main outcome variables
Quality of life; Levels of pain; Levels of spasticity; Spasticity frequency; Levels of sleep disorders due to spasticity; Stage of disease

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200408046986N1**
Registration date: **2020-05-03, 1399/02/14**
Registration timing: **prospective**

Last update: **2020-05-03, 1399/02/14**
Update count: **0**

Registration date
2020-05-03, 1399/02/14

Registrant information

Name
Saeed Shahbeigi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 7795 7666

Email address
s_shahbeigi@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-05-21, 1399/03/01

Expected recruitment end date
2020-06-20, 1399/03/31

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Safety and effectiveness of Satinex buccal spray for improving quality of life in multiple sclerosis patients

Public title

Safety and effectiveness of Satinex buccal spray

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Written Informed consent of all patients included in the study Patients diagnosed with multiple sclerosis by a specialist Stability of patients disease since one month before the study being started Patients Disease Modifying Therapy regimen should remain the same during the study

Exclusion criteria:

A history of Schizophrenia and other serious mental morbidities (Except depression and anxiety due to MS disease) A history of substance abuse Smoking and generally using cannabis (since 30 days prior to the study starting date and disability to quit during the study) and taking any other cannabis based medications (60 days prior to study starting date) taking Botulinum shot since 4 months prior to the study starting date a history of epilepsy and repetitive convulsions a history of MI and serious cardiac arrest acute liver and renal failure pregnancy and lactation Taking other investigational drugs elective surgeries and blood donation

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

block randomization method, randomized via "www.sealedenvelope.com" application; blind allocation (concealed allocation type) which means that the person allocating the participant to a group is blinded to which group (treament or control) they are allocating them to.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study patient taking drug, and the doctor who diagnoses the patients and measures outcomes, is kept blind while the researcher who analyzes the outcomes is completely aware of the circumstances

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Azad univesity of Medical Science

Street address

No 16, Azad university of medical science institutional block, western Goleyakh alley, Ayeneh Blvd., Pabarja Ave., Shariati St.

City

Tehran

Province

Tehran

Postal code

1949635881

Approval date

2019-11-20, 1398/08/29

Ethics committee reference number

IR.IAU.TMU.REC.1398.157

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

quality of life

Timepoint

Filling the MSQOL questionnaire prior to the intervention, At the end of the first, second and third month since the starting point

Method of measurement

MSQOL-54 questionnaire

2

Description

levels of spasticity

Timepoint

At the starting point and at the end of the third month of the research

Method of measurement
Modified Ashworth Scale for grading spasticity

3

Description
levels of pain
Timepoint
At the starting point and at the end of every week from the starting point
Method of measurement
Numerical Rating Scale

4

Description
Spasticity frequency (times per day)
Timepoint
At the starting point and at the end of every week from the starting point
Method of measurement
Visual Analogue Scale

5

Description
levels of sleep disorder due to spasticity
Timepoint
At the starting point and at the end of every week from the starting point
Method of measurement
Visual Analogue Scale

6

Description
disease stage
Timepoint
At the starting point and at the end of the third month of the research
Method of measurement
Expanded Disability Status Scale (EDSS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Satinex spray ,chemical ingredients: delta-9-tetrahydrocannabinol or THC (2.7 milligrams in each single 100 microliter) Cannabidiol or CBD (2.5 milligram in each single 100 microliter spray , other ingredients (as exepients : ethanol, propylene glycol, peppermint), Manufacturer: YASDAROU company, route of administration: buccal spray
Category
Treatment - Drugs

2

Description
Control group: Placebo spray (containing every ingredient in Satinex but API : ethanol, propylene glycol, peppermint oil)
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Dr Shahbeigi neurology clinic
Full name of responsible person
Saeed Shahbeigi
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No 24, Komijani Ave., Hafthowz Sq., Tehran, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yasdaru pharmaceuticals
Full name of responsible person
Gholamreza Amin
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Email
gh_amin@yahoo.com
Web page address
http://new.yasdaru.co.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No

Title of funding source
YAS DARU
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Saeed shahbeigi
Position
non faculty member specialist doctor
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Subspecialist
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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