

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Comparison of the stress response system before and after the trait social stress test (TSST) in multiple sclerosis patients

Protocol summary

Study aim

Investigating and comparing the stress response system in terms of hormonal responses and heart rate fluctuations to acute stress in MS patients before and after TSST intervention

Design

There is a group of MS patients in this study. These patients are examined five minutes before TSST (acute social stress intervention) and five minutes after salivary cortisol and heart rate intervention.

Settings and conduct

this study will be conducted in Kashani hospital affiliated to Isfahan University of medical sciences. The protocol and procedure of study will be explained and patients will be enrolled and written informed consent will be obtained. A single neurologist, a technician with a specialist with the procedure of study, and the statistical analyzer will be conducted in the study. all of them will be trained before the study by PI. In the control group (healthy people), all the above principles are observed in the same way.

Participants/Inclusion and exclusion criteria

Inclusion criteria: people between the ages of 20-50 years. Do not have systemic diseases such as DM, HTN, cardiovascular disease, and other autoimmune diseases. Do not smoke until the day before the intervention. The time of diagnosis is between 6 months and 5 years and the definitive diagnosis of MS is made by a neurologist. Exclusion criteria: dissatisfaction with participation in the study.

Intervention groups

acute stress intervention by the TSST test.

Main outcome variables

Salivary cortisol level : Heart rate variations

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171128037666N2**

Registration date: **2020-04-05, 1399/01/17**

Registration timing: **prospective**

Last update: **2020-04-05, 1399/01/17**

Update count: **0**

Registration date

2020-04-05, 1399/01/17

Registrant information

Name

Boshra Hatef

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 71 3225 3495

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-12, 1399/02/23

Expected recruitment end date

2020-06-19, 1399/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the stress response system before and after the trait social stress test (TSST) in multiple sclerosis patients

Public title

Comparison of stress system in patients with multiple sclerosis before and after TSST intervention

Purpose

Basic science

Inclusion/Exclusion criteria

Inclusion criteria:

Definitive diagnosis of MS The duration of illness ranged from 6 months to 5 years The age range is 20-50 years

No smoking during the last day

Exclusion criteria:

Having systemic diseases such as DM, HTN, cardiovascular disease, autoimmune diseases

Age

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

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **25**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Baqiyatallah University of Medical Sciences

Street address

Nasiri street, Mollasadra, Vanak

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881435916471

Approval date

2019-09-21, 1398/06/30

Ethics committee reference number

IR.BMSU.REC.1398.277

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

salivary cortisol level

Timepoint

Before and immediately after intervention

Method of measurement

ELISA kit

2

Description

Heart rate variation features

Timepoint

Before and immediately after intervention

Method of measurement

signal processing of ECG

Secondary outcomes

empty

Intervention groups

1

Description

the social stress test (TSST) use to induce stress. The period of induced stress lasts approximately 10 minutes and is divided into 5-minute components. Participants will talk about their job during the first 5 minutes of the test. The judges have been trained to maintain neutral expressions throughout the test. The presentation is immediately followed by the mental arithmetic component, during which the participant is asked to count backward from 1,022 in steps of 13. If a mistake is made, then they must start again from the beginning. This component lasts for 5 minutes and is followed by a recovery period. We will measure salivary cortisol and heart rate by ECG.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashani hospital
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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Bagheiat-allah 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
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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more data.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available