# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Nov 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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**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 scienece
**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
**City**
Tehran
**Province**
Tehran
**Postal code**
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 hosipital
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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**
Bagheiat-allah University of Medical Sciences
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Associate professor
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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