

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

20 Jun 2026

### Effects of acute stress on declarative memory reconsolidation across menstrual cycle in healthy women

#### Protocol summary

##### Summary

The purpose of this study is to examine the effects of acute stress on declarative memory reconsolidation during the menstrual cycle in healthy woman. Fifty-six healthy female students of Semnan University of Medical Sciences with naturally menstrual cycle participate in this placebo-controlled, crossover study. Participants randomly assign to eight groups according to the factors assignment (High Progesterone vs. Low Progesterone) and (Reactivation vs. No Reactivation) and (Stress vs. Control): 1. High Progesterone /Reactivation/Stress 2. High Progesterone/Reactivation/Control 3. High Progesterone/No Reactivation/Stress 4. High Progesterone/No Reactivation/Control 5. Low Progesterone/Reactivation/Stress 6. Low Progesterone/Reactivation/Control 7. Low Progesterone/No Reactivation/Stress 8. Low Progesterone/No Reactivation/Control Participants will test on three consecutive days; day 1: Learning; day 2: Memory Reactivation; and day 3: Retrieval and Recognition tests. After 2 months, participants return for days 4, 5, and 6, during which the same procedures will repeat with the alternate condition (Stress or Control) counterbalanced among participants. Menstrual status for each participant will determine by self-report and salivary progesterone levels that verifying to be within the expected range for the reported phase. 28 participants are in the follicular phase (Low progesterone), and 28 in the mid-luteal phase (High progesterone). In the stress groups, participants expose to the socially evaluated cold pressor test (SECPT) on day 2, after reactivation or no reactivation according to the corresponding group. Blood pressure and salivary cortisol will be measured to verify the efficacy of the SECPT.

#### General information

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT2014052515975N1**

Registration date: **2014-06-17, 1393/03/27**

Registration timing: **retrospective**

Last update:

Update count: **0**

#### Registration date

2014-06-17, 1393/03/27

#### Registrant information

##### Name

Mohsen Pourazizi

##### Name of organization / entity

Semnan University of Medical Science

##### Country

Iran (Islamic Republic of)

##### Phone

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#### Recruitment status

**Recruitment complete**

#### Funding source

Semnan University of Medical Sciences

#### Expected recruitment start date

2013-12-22, 1392/10/01

#### Expected recruitment end date

2014-01-21, 1392/11/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Effects of acute stress on declarative memory reconsolidation across menstrual cycle in healthy women

**Public title**

Effects of acute stress on declarative memory reconsolidation across menstrual cycle

**Purpose**

Basic science

**Inclusion/Exclusion criteria**

Inclusion Criteria: Age between 18 and 25 years; Body mass index (BMI) between 19 and 26 kg/m<sup>2</sup>; No smoking; No addiction to narcotic substance and alcohol; No reported history of disease or psychiatric problems; No medication intake; No use of psychotropic drugs; No history of disease or abnormal laboratory test; Not being in stressful situations; Having a positive mood (According to PANAS); Naturally cycling with menstrual cycles between 24 and 32 days; Consent to participate in the study. Exclusion Criteria: Being in stressful situations or disease during study.

**Age**

From **18 years** old to **25 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **56**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Crossover

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Semnan University of Medical Sciences

**Street address**

Semnan University of Medical Sciences, Semnan, Iran

**City**

Semnan

**Postal code****Approval date**

2013-11-27, 1392/09/06

**Ethics committee reference number**

92.372172

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

Stress

**ICD-10 code**

Z73.3

**ICD-10 code description**

Stress, not elsewhere classified

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

Memory retrieval

**Timepoint**

Day 3

**Method of measurement**

Number of recalled pictures

**Secondary outcomes****1****Description**

Salivary cortisol level

**Timepoint**

S1: Day 2, Before SECPT or Control condition (Base); S2: Day 2, 10 minutes after SECPT or Control ; S3: Day 2, 25 minutes after SECPT or Control; S4: Day 2, 60 minutes after SECPT or Control; S5: Day 3, Before retrieval test.

**Method of measurement**

Immunoassay- IBL kit (IBL Immuno Biological Laboratories, Hamburg, Germany)

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

In stress condition, participants expose to the socially evaluated cold pressor test (SECPT). Subjects will ask to immerse their right hand up to and including the wrist into ice water (0-2 °C). Subjects would be asking to remain immersed for 3 min, but tell that they are free to pull out at any time without penalty. During hand immersion they will videotaping, ask to look into the video camera and tell that these video recordings would be analyzed later for facial expression. The SECPT has been shown to elicit significant increases in cortisol and autonomic activity. In the control condition, individuals immerse their right hand up to and including the wrist for 3 min into warm water (35—37 °C). They are not videotape.

**Category**

Other

2

**Description**

Memory Task. Day1: Learning; On day 1, participants learn 30 pictures include ten positive pictures (such as Ice cream), ten negative pictures (example Injury) and ten neutral pictures(glass). Day2: Reactivation; On day 2, participants in reactivation group would be asked to remind the pictures they had learned on the previous day. In no reactivation group, participants reading newspaper. Immediately, they are challenging with Stress or Control. Day3: Retrieval and Recognition; On day 3, participants would be asked to write down the pictures they had learned on day 1. Cued recall will be assessed immediately after free recall. After 2 months, participants return for days 4, 5, and 6, during which the same procedures with the alternate condition (Stress or Control).

**Category**

Other

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Physiology Research Center, Semnan University of Medical Sciences

**Full name of responsible person**

Dr. Mohsen Pourazizi

**Street address**

Semnan University of Medical Sciences, Semnan

**City**

Semnan

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Semnan University of Medical Sciences, Semnan, Iran

**Full name of responsible person**

Dr. Raheb Ghorbani

**Street address**

Research and Technology Deputy of Semnan University of Medical Sciences, Basij Boulevard, Semnan, Iran

**City**

Semnan

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Semnan University of Medical Sciences, Semnan, Iran

**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**

Semnan University of Medical Sciences

**Full name of responsible person**

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**Position**

Medical Student

**Other areas of specialty/work**

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**Web page address****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*