

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### Comparing therapeutic effects of celery, dill and green tea combination with placebo in treatment of metabolic syndrome in patients with schizophrenia

#### Protocol summary

##### Summary

Schizophrenic patients are at greater risk of premature death which is mostly due to cardio vascular diseases. A major risk factor for cardiovascular accidents is metabolic syndrome . Metabolic syndrome frequency is about 30% in schizophrenic patients that is due to a basic change in body metabolism of this group or as a major side effect of neuroleptic drugs. Up to now studies failed to introduce a single ingredient for treatment of metabolic syndrome in this population that is both effective on all the aspects of this disorder( hyper-lipidemia, hyper-glycemia, high blood pressure, central obesity) and does not worsen patients psychiatric symptoms either. After studying previous reviews on the efficacy of herbal medicine on metabolic syndrome and lack of previous reports on considerable psychiatric side effects of these ingredients. We considered a double blind Randomized controlled Trial evaluating the efficacy of Celery, Dill, and Green tea on the metabolic syndrome in 60 chronic schizophrenic patients who were admitted in one of the wards of Razi psychiatry hospital. patients must have been stable for the last two month and the need for change in patients medication would exclude them from the trial. Patients were categorized into two 'case' and 'control' groups. We evaluated patients' weight, waist circumference, BP, TG, FBS, and HDL as variables indicator of metabolic syndrome prior to intervention and in 3 interval,Also patients were evaluated for side effects during the study.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013102915206N1**

Registration date: **2014-02-24, 1392/12/05**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2014-02-24, 1392/12/05

##### Registrant information

###### Name

Emytis Tavakoli

###### Name of organization / entity

University of social welfare and rehabilitation sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2218 0050

###### Email address

em.tavakoli@uswr.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

University of social welfare and rehabilitation sciences

##### Expected recruitment start date

2013-06-26, 1392/04/05

##### Expected recruitment end date

2013-09-27, 1392/07/05

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparing therapeutic effects of celery, dill and green tea combination with placebo in treatment of metabolic syndrome in patients with schizophrenia

##### Public title

therapeutic effects of celery, dill and green tea

combination in treatment of metabolic syndrome in patients with schizophrenia

#### **Purpose**

Treatment

#### **Inclusion/Exclusion criteria**

Inclusion criteria: diagnosis of schizophrenia and metabolic syndrome; age between 18 and 65 years; female; agreement of patient and her guardian towards participation in the trial. Exclusion criteria: any change in the schizophrenia medication within two months prior to the trial; coexistence of another major mental disorder; any hyper sensitive reaction to the medication; exacerbation of mental symptoms.

#### **Age**

From **18 years** old to **65 years** old

#### **Gender**

Female

#### **Phase**

N/A

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **60**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Double blinded

#### **Blinding description**

#### **Placebo**

Not used

#### **Assignment**

Parallel

#### **Other design features**

### **Secondary Ids**

empty

### **Ethics committees**

#### **1**

##### **Ethics committee**

###### **Name of ethics committee**

university of welfare and rehabilitation sciences

###### **Street address**

kodakyar Ave., daneshjo Blvd.,Evin

###### **City**

Tehran

###### **Postal code**

1985713834

##### **Approval date**

2013-06-10, 1392/03/20

##### **Ethics committee reference number**

8392

### **Health conditions studied**

#### **1**

##### **Description of health condition studied**

Schizophrenia

##### **ICD-10 code**

F20

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

Schizophrenia

### **Primary outcomes**

#### **1**

##### **Description**

Weist circumference

##### **Timepoint**

3 months

##### **Method of measurement**

By a regular meter,cm

#### **2**

##### **Description**

Blood pressure

##### **Timepoint**

3 months

##### **Method of measurement**

Pressure guage,mmHg

#### **3**

##### **Description**

Fasting blood sugar

##### **Timepoint**

3 months

##### **Method of measurement**

md/ml, evaluation of venous blood sample by spectrophotometer

#### **4**

##### **Description**

HDL(high density lipoprotein)

##### **Timepoint**

3 months

##### **Method of measurement**

mg/ml, evaluation of venous blood sample by spectrophotometer

#### **5**

##### **Description**

TG(triglycerides)

##### **Timepoint**

3 months

##### **Method of measurement**

mg/ml, evaluation of venous blood sample by spectrophotometer

### **Secondary outcomes**

## 1

### Description

Gastrointestinal discomfort

### Timepoint

3 months after intervention

### Method of measurement

Personal interview

## Intervention groups

## 1

### Description

Intervention group: prescription of tablet composed of extracts of celery, dill, and green tea three times a day half an hour before meal for 3 consecutive months.

### Category

Treatment - Drugs

## 2

### Description

Control group: prescription of a tablet with identical appearance to the herbal combination tablet three times a day half an hour before meal for 3 consecutive months.

### Category

Placebo

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Razi mental hospital

#### Full name of responsible person

#### Street address

#### City

Shahr e Rey

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

University of social welfare and rehabilitation sciences

#### Full name of responsible person

Mrs Cheraghi

#### Street address

Kkodakyar Ave., Daneshjo Blvd.,Evin

#### City

Tehran

### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

University of social welfare and rehabilitation sciences

### 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

University of social welfare and rehabilitation sciences

#### Full name of responsible person

Emytis Tavakoli

#### Position

Psychiatry resident

#### Other areas of specialty/work

#### Street address

Shahid Rastegari Blvd. Razi mental hospital

#### City

Shahr-E-Rey

#### Postal code

#### Phone

+98 21 3340 1604

#### Fax

#### Email

tavakoli79@yahoo.com; em.tavakoli@uswr.ac.ir

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

University of social welfare and rehabilitation sciences

#### Full name of responsible person

Emytis Tavakoli

#### Position

Psychiatry resident

#### Other areas of specialty/work

#### Street address

Shahid Rastegari blvd. Razi mental hospital

#### City

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569 - 18735

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#### Web page address

## Person responsible for updating data

### Contact

#### Name of organization / entity

University of social welfare and rehabilitation sciences

**Full name of responsible person**

Emytis Tavakoli

**Position**

psychiatry resident

**Other areas of specialty/work****Street address**

Razi mental hospital,Aminabad

**City**

Shahr e rey

**Postal code**

56918735

**Phone**

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**Fax****Email**

em.tavakoli@uswr.ac.ir

**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*