

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)

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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

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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