Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of green tea on BMI and anthropometric measures

Protocol summary

Summary

Comparing the changes of body mass index (BMI) and anthropometric measures at the onset of the study, 6 and 12 weeks after treatment. This clinical trial is performed in Guilan Pain Clinic on subjects whom are visited for weight loss or any other purpose. After obtaining a history, physical exam and 12 lead ECG, venous blood is obtained for baseline biochemical serum measurements, as well as CBC- ALT- AST- BUN- Cr-ALKP. The inclusion criteria are patients aged between 18-55 years old; BMI between 24 and 35 kg/m2; low tea consumption (<2 tea bags/day or <4 g loose tea/day). The exclusion criteria; competitive athletes; smokers; use of any medication, apart from over the counter and oral contraceptives; suffering from any medical or psychiatric condition; actively following a weight loss regimen or a medically prescribed dietary regime; losing or gaining >2 kg body weight in the 3 months before the start of the trial; pregnancy and breast feeding. All participants meeting inclusion criteria provide with informed consent and are randomly assigned to two groups of green tea(n=30) and placebo(n=30) by triple blocks. Subjects in green tea group receive a cup of green tea 1 hour before breakfast and lunch. At the onset of the study and after 6 and 12 weeks BMI and anthropometric measures are measured by a person who is not aware from the type of drink. Then the results will be compared between two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201504086186N10**
Registration date: **2015-04-23, 1394/02/03**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2015-04-23, 1394/02/03

Registrant information

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Bahram Naderi Nabi

Name of organization / entity
Guilan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source
Guilan University of Medical Sciences

Expected recruitment start date
2015-05-23, 1394/03/02

Expected recruitment end date
2015-12-22, 1394/10/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of green tea on BMI and anthropometric measures

Public title
Effect of green tea on BMI and anthropometric measures

Purpose
Treatment

Inclusion/Exclusion criteria

The inclusion criteria: the patient aged between 30-65 years old candidate for tibia fracture surgery; daily consumed of black tea are not more than 3 tea bags or 4 diluted ones.The exclusion criteria are cognitive or psychiatric disorders; history of any drug abuse; hepatic

and renal diseases; pregnancy and breast feeding.

Age
From **18 years** old to **55 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
Triple blocks randomization

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Guilan University of Medical Sciences

Street address
Shahid Beheshti Freeway

City
Rasht

Postal code
4193833697

Approval date
2010-09-23, 1389/07/01

Ethics committee reference number
1930596706

Health conditions studied

1

Description of health condition studied
Body Mass Index

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Body Mass Index

Timepoint
Baseline ,6 and 12 weeks after treatment

Method of measurement
Kg/m2

2

Description
Anthropometric measures

Timepoint
Baseline ,6 and 12 weeks after treatment

Method of measurement
Cm

Secondary outcomes

empty

Intervention groups

1

Description
Intervention 1: An opaque straw cup with containing 100 cc of green tea which is prepared by a tea bag containing 2 gr of green tea in 80 cc water for 2 minutes. It is prescribed 1 hour before breakfast and lunch.

Category
Treatment - Other

2

Description
Intervention 2: an opaque straw cup with containing 100 cc of warm water. It is prescribed 1 hour before breakfast and lunch.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Poursina Hospital

Full name of responsible person
Bahram Naderi Nabi

Street address
Porsina Hospital

City
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research of Guilan University of Medical Sciences

Full name of responsible person
Abtin Heidarzadeh
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Shahid Beheshti Freeway
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Rasht
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research of Guilan University of Medical 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

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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