

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

Clinical trial of the effect of *Camellia sinensis* L. and *Melissa officinalis* L. infusion on oxidative stress biomarkers (total antioxidant capacity, catalase and malondialdehyde) in welders

Protocol summary

Summary

Both of *Camellia sinensis* and *Melissa officinalis* have antioxidant effects but it is still not clear which is more effective. This study is a crossover randomized clinical trial on 20-50 years old individuals with one year welding history. They are randomly assigned into two groups, green tea (10 men) and *Melissa officinalis* (10 men), based on random numbers table. Participants receive green tea or *Melissa officinalis* as infusion 2 times a day, 2 gram each time for 4 weeks. After three weeks of washout, intervention of groups moved. Demographic information, dietary intake, anthropometric, physical activity, and oxidative stress markers (Malondialdehyde, Catalase, Total antioxidant capacity) are measured before and after of each intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015103110826N18**

Registration date: **2017-02-23, 1395/12/05**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-02-23, 1395/12/05

Registrant information

Name

Azadeh Nadjarzadeh

Name of organization / entity

Shahid Sadoughi University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 912 202 2817

Email address

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Recruitment status

Recruitment complete

Funding source

Shahid Sadoughi University of Medical Sciences of Yazd

Expected recruitment start date

2015-11-22, 1394/09/01

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of the effect of *Camellia sinensis* L. and *Melissa officinalis* L. infusion on oxidative stress biomarkers (total antioxidant capacity, catalase and malondialdehyde) in welders

Public title

Survey of the effect of *Camellia sinensis* L. and *Melissa officinalis* L. infusion on oxidative stress biomarkers in welders

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: residing in Yazd; age between 20-50 years; welding as the main job with at least one year exposure; without chronic diseases such as hypertension, heart failure, cancer, thyroid disorders, asthma, diabetes and anemia diagnosed by a physician based on self-declarations; do not drug use; do not use alcohol and without regular intake of herbal infusions.

Excluding criteria: Taking antioxidant or vitamins supplements during study; radiation therapy during study; consume less than 80% packet tea; loss to follow-up or immigration.

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: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

compare the antioxidant effects of *Camellia sinensis* and *Melissa officinalis* is done for the first time

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Sadoughi University of Medical Sciences of Yazd

Street address

Alem Square, Shohadaye Gomnam Blvd, University of Medical Sciences

City

Yazd

Postal code

Approval date

2015-08-01, 1394/05/10

Ethics committee reference number

IR.SSU.SPH.REC.1394.25

Health conditions studied

1

Description of health condition studied

Occupational exposure

ICD-10 code

Z57.5

ICD-10 code description

Occupational exposure to toxic agents in other industries

Solids, liquids, gases or vapours

Primary outcomes

1

Description

Total antioxidant capacity

Timepoint

Before and after of each intervention

Method of measurement

Reduction 1,1-diphenyl-2-picrylhydrazyl

2

Description

Malondialdehyde

Timepoint

Before and after of each intervention

Method of measurement

Colorimetry

3

Description

catalase

Timepoint

Before and after of each intervention

Method of measurement

Spectrophotometry

Secondary outcomes

empty

Intervention groups

1

Description

Group 1 consume 4 grams brewed lemon balm and twice a day for 4 weeks, then after 3 weeks wash out; consume 4 grams brewed green tea twice a day for 4 weeks

Category

Other

2

Description

Group 2 brewed 4 grams green tea and consumed twice a day for 4 weeks, then after 2 weeks wash out; brewed 4 grams *Melissa officinalis* and consumed twice a day for 4 weeks

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Industrial centers with welders
Full name of responsible person
Street address
City
Yazd

Email
fatemejafari70@gmail.com
Web page address

Person responsible for scientific inquiries

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Sadoughi University of Medical Sciences and Health Services of Yazd
Full name of responsible person
Amirhoushang Mehrparvar
Street address
Alem Square- Shohadaye Gomnam Blvd- The campus of University of Medical Sciences
City
Yazd

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Sadoughi University of Medical Sciences and Health Services of Yazd

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
Yazd University of Medical Sciences
Full name of responsible person
fatemeh jafari
Position
Msc student, Nutrition
Other areas of specialty/work
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Contact

Name of organization / entity
shahid Sadoughi University of Medical Sciences
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Person responsible for updating data

Contact

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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