

# 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

azadnajarzadeh@ssu.ac.ir

###### 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**  
**Street address**  
Department of Nutrition, School of Public Health, Shahid Sadoughi University of Medical Sciences and Health Services  
**City**  
Yazd  
**Postal code**  
**Phone**  
+98 35 3820 9100  
**Fax**

### Contact

**Name of organization / entity**  
shahid Sadoughi University of Medical Sciences  
**Full name of responsible person**  
Azadeh Najarzadeh  
**Position**  
PhD in Nutrition Sciences  
**Other areas of specialty/work**  
**Street address**  
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azadehnajarzadeh@gmail.com  
**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Yazd University of Medical Sciences  
**Full name of responsible person**  
fatemeh jafari  
**Position**  
Msc student, Nutrition  
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00  
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fatemejafari70@gmail.com  
**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*