

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 2026

### A comparative study of psychological state, oxidative stress and genotoxicity before and after use of lemon balm and cinnamon in car painters

#### Protocol summary

##### Summary

The aim of study is to explore the probable positive effects of Lemon balm and Cinnamomum zeylanicum on the paint workers through measuring blood oxidative stress markers such as total antioxidant capacity (TAC), total thiol molecules (TTM), lipid peroxidation (LPO), myeloperoxidase (MPO), and DNA damage as the marker of genotoxicity. Male painter with age range 27-50 and the least 5 work history will be included the study. Individuals with chronic disease, alcohol consumption, antioxidant consumption, and/or under drug treatment, or exposure to toxic materials, radiation therapy, or substance abuse will be excluded from the study. The study will be performed on 27 male workers who work in an industrial and farm machinery producing company. The included subjects will be administered Lemon balm and Cinnamon mixture infusion (1.5 and 0.25 g/100 mL) twice a day for 30 days at 7:00 AM and 2:00 PM every day. The Iranian version of General Health Questionnaire (GHQ28) will be used to single out high risk subjects for mental disorder, and the Iranian version of achievement motivation test (ACMT) and job satisfaction tests will be also used to evaluate achievement motivation and job satisfaction. To survey the effect of infusion on oxidative stress, before and after using mixture infusion blood sample will be collected.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013040610003N3**

Registration date: **2013-04-22, 1392/02/02**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2013-04-22, 1392/02/02

##### Registrant information

###### Name

Ali akbar Malekirad

###### Name of organization / entity

Payame Noor University

###### Country

Iran (Islamic Republic of)

###### Phone

+98 86 2422 6073

###### Email address

malekirad@tabrizu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Payame Noor University

##### Expected recruitment start date

2013-03-20, 1391/12/30

##### Expected recruitment end date

2013-05-31, 1392/03/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

A comparative study of psychological state, oxidative stress and genotoxicity before and after use of lemon balm and cinnamon in car painters

##### Public title

the effect of lemon balm and cinnamon on oxidative stress in paint workers

##### Purpose

Prevention

### Inclusion/Exclusion criteria

Inclusion Criteria: age range 27-50; male; the least 5 work history; paint workers  
Exclusion Criteria: Individuals with chronic disease; alcohol consumption; antioxidant consumption; and/or under drug treatment; or exposure to toxic materials; radiation therapy; or substance abuse

### Age

From **27 years** old to **50 years** old

### Gender

Male

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **27**

### Randomization (investigator's opinion)

N/A

### Randomization description

### Blinding (investigator's opinion)

Not blinded

### Blinding description

### Placebo

Not used

### Assignment

Single

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Pharmaceutical Sciences Research Center, Tehran  
University of Medical Science

##### Street address

Pharmaceutical Sciences Research Center, Faculty of  
Pharmacy, Tehran University of Medical Science, 16  
Azar Street, Tehran 1417614411, Iran

##### City

Tehran

##### Postal code

Tehran 1417614411

##### Approval date

2012-07-15, 1391/04/25

##### Ethics committee reference number

91-01-21:1-3

## Health conditions studied

### 1

#### Description of health condition studied

مواجهه شغلی

#### ICD-10 code

Z57.5

#### ICD-10 code description

Occupational exposure to toxic agents in other industries

## Primary outcomes

### 1

#### Description

total antioxidant capacity of serum

#### Timepoint

before and 30 day after intervention

#### Method of measurement

Ferric Reducing Ability of Plasma method

### 2

#### Description

total thiol groups

#### Timepoint

before and 30 day after intervention

#### Method of measurement

Hu method

### 3

#### Description

lipid peroxidation

#### Timepoint

before and 30 day after intervention

#### Method of measurement

thiobarbitturic acid method

### 4

#### Description

Myeloperoxidase activity

#### Timepoint

before and 30 day after intervention

#### Method of measurement

Elisa Method

### 5

#### Description

deoxyribonucleic acid Damage

#### Timepoint

before and 30 day after intervention

#### Method of measurement

Elisa method

## Secondary outcomes

### 1

#### Description

General Health

#### Timepoint

before the intervention

#### Method of measurement

GHQ questionnaire

## Intervention groups

1

### Description

The included subjects will be administered Lemon balm and Cinnamon mixture decoction (1.5 and 0.25 g/100 mL) twice a day for 30 days at 7:00 AM and 2:00 PM every day.

### Category

Prevention

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Hepco Company, Arak, Iran

#### Full name of responsible person

Ahmad Gogarzi

#### Street address

#### City

Arak

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Payame Noor University

#### Full name of responsible person

Mehdi Kiani

#### Street address

Amanipou Alley, Khoram Street, Payame Noor University

#### City

Arak

### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

Payame Noor University

### 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

Payame Noor University

### Full name of responsible person

Ali Akbar Malekirad

### Position

PhD.assistant prof.

### Other areas of specialty/work

### Street address

Amanipour Alley, Khoram street

### City

Arak

### Postal code

### Phone

+98 86 1223 5541

### Fax

### Email

ak\_malekirad@yahoo.com

### Web page address

## Person responsible for scientific inquiries

### Contact

### Name of organization / entity

Faculty of Pharmacy and Pharmaceutical Sciences  
Research Center, Tehran University of Medical Science

### Full name of responsible person

Mohammad Abdollahi

### Position

Prof. of Toxicology

### Other areas of specialty/work

### Street address

Pharmaceutical Sciences Research Center, Faculty of Pharmacy, Tehran University of Medical Science, 16 Azar Street, Tehran 14176146411, Iran.

### City

Tehran

### Postal code

### Phone

+98 21 6648 2703

### Fax

### Email

Mohammad@TUMS.Ac.Ir

### Web page address

## Person responsible for updating data

### Contact

### Name of organization / entity

Payame Noor University

### Full name of responsible person

Ali Akbar Malekirad

### Position

Assistant prof. of Physiology

### Other areas of specialty/work

### Street address

Amanipour Alley, khoram street, Arak, Iran

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### Postal code

### Phone

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**Fax**

**Email**

ak\_malekirad@yahoo.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*