# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

06 Nov 2026

## Assessment of anti-oxidant and anti-inflammatory properties of green tea hydroalcoholic extract on oxidative-stress factors in patients with pneumonia hospitalized at ICU in Ziaeian teaching hospital

## Protocol summary

**Summary**

In order to find an efficient anti-oxidant and evaluate anti-oxidant property of green tea we decided to use it in critically ill pneumonia patients with SIRS. In this study dried green tea is bought from Lahijan, Iran. Tea leaves are grinded, extracted by hydro alcoholic solvent and then dried. Extract standardization based on poly phenolic content performed by Total phenolic assay and total antioxidant power. Twenty ICU patients are divided randomly in two groups. As a single blind study, Group one will receive standardized extract containing 130 milligrams of poly phenol and group two will receive placebo, both groups three times a day at 8 AM, 2 PM and 8 PM for one week. Blood sample will be taken on day 0 before administration, days 3 and 7 after five hours from the last administration. Total thiol, total anti-oxidant power and IL-6 plasma levels will be measured.

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT2016092529327N2**
Registration date: **2016-10-25, 1395/08/04**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

**Registration date**

2016-10-25, 1395/08/04

**Registrant information**

**Name**

Ramin Abrishami

**Name of organization / entity**

Islamic Azad University, Pharamceutical sciences branch

**Country**

Iran (Islamic Republic of)

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**Recruitment status**

**Recruitment complete**

**Funding source**

Islamic Azad University of Pharmaceutical Science, Investigator

**Expected recruitment start date**

2016-10-01, 1395/07/10

**Expected recruitment end date**

2017-04-01, 1396/01/12

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Assessment of anti-oxidant and anti-inflammatory properties of green tea hydroalcoholic extract on oxidative-stress factors in patients with pneumonia hospitalized at ICU in Ziaeian teaching hospital

**Public title**

Assessment of anti-oxidant and anti-inflammatory properties of green tea in ICU patients

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: ICU admission less than 1 week ; SIRS positive ; APACHE Score higherthan 10 ; Pneumonia diagnosis ; Tea consumption history Exclusion criteria : being NPO ; pregnancy ; age less than 18 years

**Age**
From **18 years** old
**Gender**
Both

**Phase**
2
**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**
Used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics committee of Islamic Azad University of Pharmaceutical Sciences
**Street address**
#99, Yakhchal Ave., Shariati st.
**City**
Tehran
**Postal code**
**Approval date**
2016-05-17, 1395/02/28
**Ethics committee reference number**
IR.IAU.PS.REC.1395.6

## Health conditions studied

### 1

**Description of health condition studied**
Pneumonia
**ICD-10 code**
J15, J14,
**ICD-10 code description**
Pneumonia due to Streptococcus pneumoniae, Pneumonia due to Haemophilus influenzae, Bacterial pneumonia, not elsewhere classified

## Primary outcomes

### 1

**Description**
Total anti-oxidant power
**Timepoint**
Day 0, 3, 7
**Method of measurement**
FRAP

### 2

**Description**
Total plasma thiol
**Timepoint**
Day 0, 3, 7
**Method of measurement**
Ellman method

### 3

**Description**
interleukin 6
**Timepoint**
Day 0, 7
**Method of measurement**
ELISA

## Secondary outcomes

### 1

**Description**
lenth of stay
**Timepoint**
at the end of the study
**Method of measurement**
mathematical

### 2

**Description**
mechanical ventilation days
**Timepoint**
at the end of the study
**Method of measurement**
mathematical

### 3

**Description**
APACHE II score
**Timepoint**
day 0,7
**Method of measurement**
medical calculator

## Intervention groups

### 1

**Description**
Intervention group will receive standardized extract containing 130 milligrams of poly phenol three times a

day at 8 AM, 2 PM and 8 PM for one week

**Category**

Treatment - Drugs

**2**

**Description**

Control group will receive placebo three times a day at 8 AM, 2 PM and 8 PM for one week

**Category**

Placebo

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Ziaeian Hospital

**Full name of responsible person**

Zohre Labbani Motlagh

**Street address**

**City**

Tehran

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Islamic Azad University of Pharmaceutical Science

**Full name of responsible person**

zohre Labbani Motlagh

**Street address**

#99, Yakhchal Ave, Shariati st.

**City**

tehran

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Islamic Azad University of Pharmaceutical Science

**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**

Islamic Azad University of Pharmaceutical Sciences

**Full name of responsible person**

Ramin Abrishami

**Position**

Assistant professor

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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*