

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 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 Ziaeeian 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, Pharmaceutical sciences branch

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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 Ziaeeian 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**

length 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

Ziaei 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 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