

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### The effect of green tea extract on some inflammatory biomarkers(IL 6, IL1 $\beta$ ,TNF $\alpha$ ,CRP), serum total antioxidant capacity(TAC), MDA and Disease activity in patients with Systemic lupus erythematosus

#### Protocol summary

##### Summary

Aim of this study is to determine and compare the efficacy of green tea extract on inflammatory markers including IL 1 $\beta$ , IL 6, CRP, TNF  $\alpha$ , total antioxidant capacity (TAC), MDA and severity of the disease in lupus patients in two groups of intervention and control . This study is a randomized, double-blind clinical trial. The subjects are systemic lupus erythematosus patients. This study is in the second phase of clinical trial. The subjects are patients older than 15 years who have had 4 diagnosis criteria's of lupus. These include clinical and immunological criteria's. Study participants were randomly divided into 2 groups of intervention( capsules of green tea extract) and control group (capsule of cellulose). Exclusion criteria are as follow: patients with other autoimmune diseases; infectious or liver disease; patients with creatinine higher than 2.5 and the women who are pregnant. The sample were found to be 76. The patients in intervention group are given daily dose of 1000mg of aqueous green tea extract (of 6 gram of dried green tea leaf) in form of two capsules ( 500 mg). Also in control group, the patients are given daily dose of 1000mg of cellulose in form of two capsules ( 500 mg). Duration of treatment is three months. Measured variables at baseline and after 12 weeks include Inflammatory factors ( IL 6, IL 1 $\beta$  , TNF  $\alpha$ ), CRP, MDA, serum total antioxidant capacity(TAC) and disease activity.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015091924059N2**  
Registration date: **2016-02-20, 1394/12/01**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-02-20, 1394/12/01

##### Registrant information

###### Name

Zahra Shamekhi

###### Name of organization / entity

Ahvaz university of medical sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 61 3373 8253

###### Email address

shamekhi.z@ajums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Ahvaz University of Medical Sciences, Vice chancellor for research

##### Expected recruitment start date

2015-09-23, 1394/07/01

##### 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

The effect of green tea extract on some inflammatory biomarkers(IL 6, IL1 $\beta$ ,TNF  $\alpha$ ,CRP), serum total antioxidant capacity(TAC), MDA and Disease activity in patients with Systemic lupus erythematosus

## Public title

Effect of green tea on treatment of lupus

## Purpose

Other

## Inclusion/Exclusion criteria

Inclusion criteria : patients older than 15 years who have had 4 diagnosis criteria's of lupus. These include clinical and immunological criteria. Exclusion criteria: patients with other autoimmune diseases; infectious or liver disease; patients with creatinine higher than 2.5 and women who are pregnant.

## Age

No age limit

## Gender

Both

## Phase

2

## Groups that have been masked

No information

## Sample size

Target sample size: 76

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

In randomized , table of random numbers was used.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee Of Ahvaz University of Medical Sceinces

##### Street address

Vice chancellor for research of Ahvaz University of Medical Sceinces, golestan highway, Ahvaz, Iran

##### City

Ahvaz

##### Postal code

61357,15794

#### Approval date

2015-07-25, 1394/05/03

#### Ethics committee reference number

IR.AJUMS.REC.1394.251

## Health conditions studied

### 1

#### Description of health condition studied

Systemic lupus erythmatous

#### ICD-10 code

M32.9

#### ICD-10 code description

Systemic Lupus Erythematosus, unspecified

## Primary outcomes

### 1

#### Description

Disease Activity

#### Timepoint

Three months after starting of intervention

#### Method of measurement

Determination of disease activity is done through SLEDAI ( systemic lupus erythmatous disease activity index ) questionnaire.

## Secondary outcomes

### 1

#### Description

(IL6,IL1 $\beta$ , TNF $\alpha$ ,CRP),MDA ,serum total antioxidant capacity

#### Timepoint

At baseline and after three months of intervention

#### Method of measurement

Comparison of variables of each group before and after intervention

## Intervention groups

### 1

#### Description

Intervention group: Patients are given daily dose of 1000mg aqueous green tea extract (of 6 grams of dried green tea leaf) in the form of 2 capsules( 500 mg) for three months.

#### Category

Treatment - Drugs

### 2

#### Description

Control group : Patients in Control group receive daily dose of 1000 mg cellulose in the form of 2 capsules ( 500 mg) for three months

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

Name of recruitment center

Lupus clinic, Hafez hospital, Shiraz University of Medical Sciences

**Full name of responsible person**

Zahra Shamekhi

**Street address**

Lupus clinic, Hafez hospital, Shiraz University of Medical Sciences, Abivedi street, Shiraz, Iran

**City**

Shiraz

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Vice chancellor for research , Ahvaz university of medical sciences

**Full name of responsible person**

Zahra Shamekhi

**Street address**

Ahvaz University of medical sciences, golestan high way, Ahvaz, Iran

**City**

Shiraz

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Vice chancellor for research , Ahvaz university of medical sciences

**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**

Ahvaz university of medical sciences

**Full name of responsible person**

Zahra Shamekhi

**Position**

Ph.D student

**Other areas of specialty/work**

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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*