Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

The effect of green tea extract on some inflammatory biomarkers(IL 6, IL1β,TNF α,CRP), serum total antioxidant capacity(TAC), MDA and Disease activity in patients with Systemic lupus erythematous

Protocol summary

Summary

Aim of this study is to determine and compare the efficacy of green tea extract on inflammatory markers including IL 1β, IL 6, CRP, TNF α, 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 erythematous 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 1β , TNF α), 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

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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, IL1β,TNF α,CRP), serum total antioxidant capacity(TAC), MDA and Disease activity in patients with Systemic lupus erythematous

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) questionnare.

Secondary outcomes

1

Description
(IL6,IL1β, TNFα,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 Sceinces

Full name of responsible person

Zahra Shamekhi

Street address

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

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research , Ahvaz university of medical sceinces

Full name of responsible person

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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 sceinces

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 sceinces

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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