Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Aug 2026

Beneficial effects of N-acetylcysteine on systemic lupus erythematosus disease activityand its associated complications

Protocol summary

Study aim
Beneficial effects of N-acetylcysteine on systemic lupus erythematosus disease activityand its associated complications

Design
After selecting patients based on inclusion criteria, patients were randomly divided into two groups randomly

Settings and conduct
All patients were routinely examined and periodically tested at baseline. These tests included cell blood count, kidney and renal function, urine analysis, and laboratory tests for lupus (Anti dsDNA, ANA titer, C3, C4, proteinuria, and CH50) performed in the reference laboratory of Imam Khomeini Hospital employing appropriate and routine methods. according to BILAG and the SLEDAI score disease activity is measured. Duration of follow up is 3 months after treatment. All patients are told to avoid any change in the drug pattern and other nutritional or behavioral habits. It should be noted that a daily allowance dose of multivitamin contained 500 mg of vitamin C and 30 IU of vitamin E in these patients. finally all data are recorded in pre-designed information forms.

Participants/Inclusion and exclusion criteria
The inclusion criteria are: age more than 16 years old; patients with lupus; history of taking prednisone, azathioprine, mycophenolate mofetil and also satisfaction with participation in the study. Exclusion criteria also are pregnant or lactating patients or people with chronic infections, bronchiectasis; last month infections; severe and recurrent infections; smoking; patients with excessive use of antioxidants (daily and without prescription) and acetaminophen; acute SLE flares threatening vital organs, and people in need of treatment with intravenous cyclophosphamide and biological drugs of rituximab and abatacept

Intervention groups
Control group (routine treatment for lopus), intervention group (receiving N acetyl cysteine)

Main outcome variables
The activity of lupus disease

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181030041500N2**
Registration date: **2019-07-08, 1398/04/17**
Registration timing: **retrospective**

Last update: **2019-07-08, 1398/04/17**
Update count: **0**

Registration date
2019-07-08, 1398/04/17

Registrant information

Name
pooya saeed askari

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 34 3281 2464

Email address
p.saeedaskari@rums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2014-06-22, 1393/04/01

Expected recruitment end date
2014-09-21, 1393/06/30

Actual recruitment start date
2014-05-22, 1393/03/01

Actual recruitment end date

2014-09-21, 1393/06/30

Trial completion date

2015-02-19, 1393/11/30

Scientific title

Beneficial effects of N-acetylcysteine on systemic lupus erythematosus disease activityand its associated complications

Public title

Beneficial effects of N-acetylcysteine on systemic lupus erythematosus disease activityand its associated complications

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age more than 16 Having lupus History of using prednisone, azathioprine, mycophenolate mofetil Satisfaction with participation in the study

Exclusion criteria:

Pregnant or lactating patients Having any disease at the same time History of chronic infections Bronchiectasis Infection in last month History of severe infections or frequent infections Smoking Patients with excessive use of antioxidants (daily and without Prescription) and acetaminophen Acute SLE flares threatening vital organs People in need of treatment with intravenous cyclophosphamide Patients who are candidates for biological drugs rituximab, abatacept Dissatisfaction for participation in the study

Age

From **16 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **80**

Actual sample size reached: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Tools used in randomization was table of random numbers.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Rafsanjan university of medical sciences

Street address

Central organisation, Emam Ali Blvd

City

Rafsanjan

Province

Kerman

Postal code

7717933777

Approval date

2018-08-29, 1397/06/07

Ethics committee reference number

IR.RUMS.REC.1397.100

Health conditions studied

1

Description of health condition studied

Systemic Lupus erythromatosis

ICD-10 code

M32

ICD-10 code description

Systemic lupus erythematosus (SLE)

Primary outcomes

1

Description

The activity of lupus disease

Timepoint

At the beginning of study and 3 months later

Method of measurement

SLEDAI and BILAG scoring protocol

Secondary outcomes

empty

Intervention groups

1

Description

Control group: the patients continue standard drugs protocol

Category

Treatment - Drugs

2

Description

Intervention group: the patients receive 1800 mg NAC (made by osveh drug company, 600 mg tab) for 3

months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rheumatology clinic of Emam khomeini Hospital

Full name of responsible person

Seyed Reza Najafi

Street address

Chamran Highway, Tehran, Tehran province

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1419733141

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Imamhospital@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Seyyed Reza Najafi

Street address

Central Organisation of Tehran University of Medical Sciences, Ghods Ave, Keshavarz Blvd.

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rmo@tums.ac.ir

Grant name

Tehran University of Medical Sciences

Grant code / Reference number

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

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Pooya Saeed Askari

Position

Medical student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available