Assessing the Impact of Herbal Supplement on Fatigue and Disease Activity in SLE: Results from an 8-Week Randomized Trial

20-01-2026

Introduction

Systemic lupus erythematosus (SLE) is a chronic auto-immune disease with a wide range of clinical manifestations and a complex pathogenesis. Despite advancements in treatments for disease activity, fatigue continues to be one of the most prominent and unresolved complaints among patients [1].

According to Jianhua Shen et al. [2], fatigue is defined as an overwhelming sense of tiredness, a lack of energy, and a feeling of exhaustion that is associated with impaired physical and/or cognitive functioning. The prevalence of fatigue in SLE may reach up to 90%, according to some studies[3]. Moreover, over 50% of patients report it as their most disabling symptom[3]. Stress, depression, pain, disease activity, and disease duration are among the most common contributors to fatigue in these patients. Fatigue significantly impacts quality of life (QoL) across all domains physical, psychological, and socio-occupational. Management recommendations for fatigue typically involve a combination of pharmacologic and nonpharmacologic approaches; however, no specific medications have been shown to be effective in treating fatigue associated with SLE[4].Hence, it is essential to evaluate and identify potential intervention areas to alleviate patients' symptom burden and enhance their overall quality of life.

Therefore, we opted for the dietary supplement EVACUR.It is a dietary supplement designed to help combat fatigue and boost the immune system. It combines natural extracts, vitamins, and selenium to support overall vitality.

The aim of our double-blind, placebo-controlled randomized trial was to evaluate the efficacy of using herbal-based treatment on patients with SLE-related fatigue .

Methods:

Study Type:

This was a randomized, double-blind clinical trial conducted in two internal medicine departments in Tunisia over a period of 3 months.

Study Population:

Patients with a diagnosis of SLE who were being followed in the participating departments.

Inclusion Criteria:

- Age > 18 years
- Confirmed diagnosis of SLE according to the 2019 ACR/EULAR classification criteria
- Presence of fatigue, defined as a FACIT-F score < 34
- Signed informed consent

Non-Inclusion Criteria:

- Pregnancy or breastfeeding
- Diseases or comorbidities that may influence fatigue:untreated hypothyroidism, psychosis common infections, and other autoimmune and inflammatory diseases
- Patients on vitamin K antagonist therapy, due to a possible interaction with Ginger and Nigella
- History of severe allergy or intolerance to EVACUR or any component of the placebo

Exclusion Criteria:

- Diagnosis of another systemic disease during the study period
- Pregnancy
- Allergy to any component of EVACUR
- Withdrawal of consent

Data Collection:

Patient data were collected from medical records,including epidemiological characteristics such as age at inclusion , gender and medical and family history .Disease-specific data included the duration disease,

systemic manifestations,nature of treatement at inclusion .Disease activity was evaluated using clinical SLEDAI-2K score. Baseline FACIT score was collected.Biological assessments were performed such us Anti-dsDNA antibody titers ,ANA and serum C3 and C4 levels.

Study protocol:

Randomization:

A two -to-one (2:1) randomization was performed in this study in which patients were randomly assigned into two groups: Group 1 (G1) which received EVACUR, and Group 2 (G2) received a placebo. Randomization was handled by an independent third party using a dedicated randomization software.

Double-Blind Design:

Neither the patients nor the investigators knew the treatment assignment. EVACUR and placebo capsules are identical in appearance.

Treatement:

EVACUR:

A phytotherapeutic compound presented in capsule form. Each bottle contains 40 capsules composed of: Nigella seed, Zinc sulfate, Echinacea, Vitamin C, Red ginseng, Ginger, Chamomile, Spirulina, Royal jelly, Ganoderma, Vitamins B1, B6, B12, Selenium(**Table1**).

Contra-indications: Allergy to any component of the supplement.

Placebo:

Capsules containing starch, packaged identically to EVACUR bottles.

Both treatments will be administered at a dose of 2 capsules per day in the morning (3 bottles per patient for the study duration).

Follow-up:

Patients attended three visits at baseline**M0**, one month**M1**, and two months**M2**. The FACIT score was assessed during each visit along with a physical examination.

Adverse Events:

Potential side effects will be recorded and evaluated throughout the study. Occurrence of any adverse event will lead to patient exclusion and trigger a pharmacovigilance investigation. All adverse events must be reported immediately to the principal investigator.

Fatigue Assessment Score:

Functional Assessment of Chronic Illness Therapy – Fatigue (FACIT-F)

A 13-item questionnaire with responses on a Likert scale from 1 (not at all) to 5 (very much).

Total score out of 52; higher scores indicate less fatigue.Can be calculated if at least 50% of the questions are answered.

Reliability: High (Cronbach's alpha = 0.94)

Validity: Strong, with good correlation with other fatigue measurement tools

Completion time: 5–10 minutes

A validated Arabic version is available with good psychometric properties .

Evaluation Criteria:

Primary Endpoint:

A mean Facit-F score improvement between G1 and G2 at month2 > Minimal Clinically Important Difference(MCID).The MCID in SLE is estimated at 3.4T[5].

Secondary Endpoints:

Improvement in the disease activity SLEDAI score

Good tolerance of the dietary supplement.

Statistical Analysis:

Data were analyzed using SPSS.Appropriate statistical tests will be applied, including Student's t-test or the Wilcoxon test.Randomization will be conducted using dedicated software.

Ethical considerations

This study was conducted according to the Declaration of Helsinki and approved as well by the RABTA hospital's ethics committee under the number of CERB33/2023. Informed consent was given by each patient before starting the study.Each patient will be assigned an inclusion number used for randomization and data entry, ensuring patient confidentiality.

Statements & declarations:

- **Funding**: Wellnet Pharmaceutical Factory ® provided the dietary supplement and the placebo free of charge.No additional funding was required

- **Conflict of Interest**:. Wellnet Pharmaceutical Factory® had no role in the study design, data collection, analysis, interpretation, or decision to submit the manuscript for publication.

-Informed consent

Informed consent was obtained from all individual participants included in the study after reading and agreeing with the details of this trial.

- **Availability of data and material** :data are available on request from the authors

- **Ethics approval** :Patients' anonymity was maintained throughout the study. The study was approved by the ethics committee of the hospital under the number CERB 33/2023.

Table 1. Ingredients and Dosage of EVACUR Formulation per Capsule

Ingredient	Latin/INCI Name	Form/Quality	Quantity per capsule
Black seed	Nigella sativa	Dry extract	80 mg
Echinacea	Echinacea spp.	Dry extract	40 mg
Ginger	Zingiber officinale	Dry extract	30 mg
Chamomile	Matricaria chamomilla	Dry extract	10 mg
Red ginseng	Panax ginseng	Dry extract	10 mg
Reishi mushroom	Ganoderma lucidum	Dry extract	10 mg
Spirulina	Spirulina spp.	Dry extract	60 mg
Royal jelly	Royal jelly	Lyophilized	20 mg
Vitamin C	Ascorbic acid	—	30 mg
Zinc	Zinc sulfate	—	2.5 mg
Vitamin B1	Thiamine	—	3 mg
Vitamin B6	Pyridoxine	Marine source	4 mg
Vitamin B12	Cobalamin	—	10 µg
Selenium	Selenium yeast	—	40 µg