ISRCTN59058825 https://doi.org/10.1186/ISRCTN59058825

The effect of vitamin D supplementation in patients with systemic lupus erythematosus

Submission date	Recruitment status	[_] Prospectively registered
28/02/2021	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/04/2021	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
31/03/2026	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol

Background and study aims
Systemic lupus erythematosus, the most common form of lupus, is a chronic autoimmune disease that can cause severe fatigue and joint pain.
Vitamin D deficiency is common in SLE patients due to sun avoidance. The aim of this study is to analyse the effect of vitamin D supplementation on disease activity and fatigue in SLE patients who are vitamin D deficient or insufficient.

Who can participate?
SLE patients who fulfil the SLICC classification criteria for SLE, are over the age of 18 and have been diagnosed with vitamin D deficiency and insufficiency may participate.

What does the study involve?
The study involves an interview, filling in questionnaires and blood sampling at baseline and after 6 and 12 months of vitamin D supplementation.

What are the possible benefits and risks of participating?
The benefits of participating include being provided with free vitamin D supplementation for 1 year. The risks are very minimal and include potential side effects from vitamin D supplementation.

Where is the study run from?
The study is run from Mater Dei Hospital (Malta)

When is the study starting and how long is it expected to run for?
August 2016 to August 2018

Who is funding the study?
The Faculty of Medicine and Surgery, University of Malta provided funding for this research. Quest NutraPharma sponsored the vitamin D3 supplementation but did not have any input with regards to setting up the protocol or conducting this research.

Who is the main contact?
Rosalie Magro, rosaliemagro@gmail.com

Contact information

Type(s)
Scientific

Contact name
Dr Rosalie Magro

ORCID ID
https://orcid.org/0000-0001-8486-8410

Contact details
Department of Medicine
Mater Dei Hospital
Msida
Malta
MSD2090
+35625450000
rosaliemagro@gmail.com

Additional identifiers

Protocol serial number
54/2016

Study information

Scientific Title
Vitamin D supplementation in systemic lupus erythematosus: relationship to disease activity, fatigue and the interferon signature gene expression

Study objectives
Vitamin D supplementation in SLE results in improved disease activity, particularly when vitamin D is deficient.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/10/2016, University Research Ethics Committee, Malta Medical School, University of Malta (Msida, Malta; +356 23401214; research-ethics.committee@um.edu.mt), ref: 54/2016

Primary study design
Interventional

Study design
Single centre interventional open-label study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Treatment of vitamin D deficiency/insufficiency in patients with systemic lupus erythematosus

Interventions
SLE patients with vitamin D deficiency or insufficiency are supplemented with vitamin D3 8000IU daily for 8 weeks if they are vitamin D deficient, or 8000IU daily for 4 weeks if they are insufficient. This is followed by 2000IU daily maintenance. They are assessed at baseline, after 6 and 12 months by means of an interview, filling in questionnaires and blood tests.

Intervention Type
Supplement

Primary outcome(s)
Systemic lupus erythematosus disease activity measured using SLEDAI-2K at baseline, 6 months and 12 months

Key secondary outcome(s)
1. Fatigue measured using Fatigue Severity Scale at baseline, 6 and 12 months
2. Interferon signature gene expression measured using quantigene analysis at baseline and 6 months

Completion date
20/08/2018

Eligibility

Key inclusion criteria
1. Fulfills the SLICC classification criteria for SLE
2. Age ≥18 years
3. The presence of vitamin D deficiency/insufficiency

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit

120 Years

Sex
All

Total final enrolment
33

Key exclusion criteria
Patients with stage 4 and 5 chronic kidney disease

Date of first enrolment
03/11/2016

Date of final enrolment
20/07/2017

Locations

Countries of recruitment
Malta

Study participating centre
Mater Dei Hospital
Tal-Qroqq
Msida
Malta
MSD2090

Sponsor information

Organisation
University of Malta

ROR
https://ror.org/03a62bv60

Funder(s)

Funder type
University/education

Funder Name
Università ta' Malta

Alternative Name(s)
L-Università ta' Malta, University of Malta, The University of Malta, UM

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Malta

Results and Publications

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		03/12/2021	17/08/2022	Yes	No