

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

Submission date 28/02/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 12/04/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 17/08/2022	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data

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
<http://orcid.org/0000-0001-8486-8410>

Contact details
Department of Medicine
Mater Dei Hospital
Msida
Malta
MSD2090
+35679491959
rosaliemagro@gmail.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Study design

Single centre interventional open-label study

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

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 measure

Systemic lupus erythematosus disease activity measured using SLEDAI-2K at baseline, 6 months and 12 months

Secondary outcome measures

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

Overall study start date

25/08/2016

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

40

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

Sponsor details

Faculty of Medicine and Surgery

Tal-Qroqq

Msida

Malta

MSD2080

+356 2340 2340

info@um.edu.mt

Sponsor type

University/education

Website

<http://www.um.edu.mt/>

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

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

Intention to publish date

01/03/2021

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