A Mono-center, Prospective Study for the Collection of Blood Samples From Patients With Systemic Lupus Erythematosus (SLE) and volunteers in good health for research purposes.

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Ethical review	Not approved
Status	Will not start
Health condition type	Autoimmune disorders
Study type	Observational invasive

Summary

ID

NL-OMON55993

Source
ToetsingOnline

Brief title
ERM-COL-001

Condition

- Autoimmune disorders

Synonym
Lupus Erythematosus (SLE) and Lupus

Research involving
Human

Sponsors and support

Primary sponsor: Ermium Therapeutics
Source(s) of monetary or material Support: de sponsor van de studie Ermium Therapeutics SAS

Intervention

Keyword: Blood samples, Lupus, mono-center, prospective study

Outcome measures

Primary outcome

- investigate the immune system to support the discovery and development of

new molecules for the potential treatment of SLE and other autoimmune diseases

- to evaluate the effect in vitro of these new molecules on the dysregulated

immune system. .

Secondary outcome

n/a

Study description

Background summary

nd Development of orally available drug candidate molecules to modulate the dysregulated immune system. These drug candidates have the potential to address a wide range of chronic auto-immune diseases, affecting millions of people worldwide and include type I interferon-mediated diseases, like systemic lupus erythematosus (SLE).
In response to an unknown trigger, the immune system may attack the body*s own tissues or organs leading to life threatening conditions for some patients.
Treatment for autoimmune diseases generally focuses on reducing immune system activity. Most of these diseases have no cure and the most serious conditions require lifelong treatment to ease symptoms.
One of the auto-immune diseases, Ermium is targeting is SLE.
Lupus is a systemic autoimmune disease in which abnormal antibodies directed against healthy tissues and organs cause disease and damage. Inflammation caused by lupus can affect many organ systems, including skin, joints, kidneys,

blood cells, brain, heart and lungs.
Systemic lupus is a heterogeneous disease affecting people in different ways. For some, lupus can be mild and limited for others, it may cause disease and damage in critical organs and may be life threatening.
Most people with lupus have disease characterized by episodes or flares when signs and symptoms worsen for a while, then improve or even disappear completely for a time.
The global incidence is 3,41 million people(1). It is estimated that there are 200.000-250.000 patients in Europe(2) living with lupus and about1,5 million of people in the United States(3).
In this study, Ermium aims to collect blood samples from SLE patients to investigate the immune system to support the discovery and development of new molecules for the potential treatment of SLE and other autoimmune diseases, and to evaluate the effect in vitro of these new molecules on the dysregulated immune system. In vitro assays on whole blood, isolated blood cells, serum/plasma may be performed to study the immune system as well as the immune response induced by those new molecules as potential new treatment option for SLE. Different (cell-based) assays may be run using a range of immunological techniques, but no genetic testing will be performed.

Study objective

The primary objective of this study is to collect blood samples (maximum of 150 mL per study visit) from women and men who have SLE and from volunteers in good health to study the immune system of SLE patients and to investigate new potential molecules.

Study design

Enrolled subjects will provide one standard venous blood draw performed under the responsibility of a trained investigator.
Subjects may choose to participate in this study only once or may be allowed to attend multiple visits (every 3 months) if required.
Whole blood samples will be shipped ambient on the day of collection for further processing and analysis to the laboratory site of the Sponsor in France.
Research protocols may be performed at the Sponsor*s lab using fresh blood or isolated immune cells, and remaining serum/plasma as well as whole blood and isolated immune cells will be aliquoted and stored for further exploratory research work. Some studies will require fresh samples while others can be performed using frozen and thawed blood cells.
No genetic testing will be performed, nor will blood samples be used for transfusion or stem cell related applications.
Since the blood samples will be used for exploratory Research activities, it is not possible to estimate the exact sample size for the study. However, at this time, it is projected that samples from less than 150 subjects will be required to complete the entirety of the research work.

The study duration is approximately 3 years, but may be ended earlier if sufficient samples are collected.
All study staff will be well trained on the study protocol and have current certifications for the roles they will perform in this study.
Study subjects will be consented, enrolled, and have blood drawn in a private area of the study center. Subjects will be given ample time to decide to participate after all their questions have been answered.
The investigator will be allowed to delegate the ICF to a trained staff member (i.e study nurse).

Intervention

one blood sample of 150 ml will be taken.

Study burden and risks

The possible risks with blood drawing are pain, bleeding, fainting, bruising, infection and/or hematoma (blood clot under the skin) at the injection site. If the subjects develops bruising this will go away after a couple of days and can be treated with warm compresses.

Contacts

Public
Ermium Therapeutics

Rue De Faubourg Saint-Jacques 29
Paris 75014
FR
Scientific
Ermium Therapeutics

Rue De Faubourg Saint-Jacques 29
Paris 75014
FR

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• SLE diagnosis according to ACR criteria (for SLE patients) or volunteer in good health
• Able to read and und understand an informed consent form written in Dutch
• Willing to provide a blood sample
• Age > 18 years with no upper age limit
• Agree to comply with all study procedures and requirements.

Exclusion criteria

• Unable to undergo blood sample collection
• Blood transfusion or donation within 3 months prior to signing ICF
• Participation in any other (interventional) study within 3 months prior to signing ICF
• If female of childbearing potential, must not be pregnant or lactating
• Any condition that in the opinion of the Investigator should preclude participation in the study.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	150

Type:	Anticipated

Ethics review

Not approved

Date:	04-12-2023
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL85260.075.23