

# Ocular manifestations in rheumatologic diseases in adults

<b>Submission date</b> 23/08/2023	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 27/09/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 27/09/2023	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Rheumatic diseases are systemic immune diseases that affect all body organs including the eye. Many rheumatic diseases have been related to specific ocular (eye) involvement, such as systemic lupus erythematosus (SLE), Sjögren syndrome (SS), spondyloarthropathies (SPA), vasculitis, and others. The aim of this study is to study the prevalence of ocular manifestations in rheumatic diseases.

### Who can participate?

Patients older than 18 years with rheumatic disease with ocular symptoms

### What does the study involve?

The participants' demographic data and history regarding the disease were recorded. Eye examinations included visual acuity, slit lamp examination, dry eye tests, dilated fundus examination, and intraocular pressure.

### What are the possible benefits and risks of participating?

There are no expected benefits or risks of participating.

### Where is the study run from?

Damascus University (Syria)

### When is the study starting and how long is it expected to run for?

June 2020 to June 2023

### Who is funding the study?

Investigator initiated and funded

### Who is the main contact?

Dr Daa Haj Ali, [diaaali907@gmail.com](mailto:diaaali907@gmail.com)

## Contact information

**Type(s)**

Scientific

**Contact name**

Dr Diaa Haj Ali

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**Contact details**

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**Additional identifiers****EudraCT/CTIS number**

Nil known

**IRAS number****ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

Nil known

**Study information****Scientific Title**

Ocular manifestations in rheumatologic diseases in adults

**Study objectives**

To study the prevalence of ophthalmic manifestations in rheumatic diseases.

**Ethics approval required**

Ethics approval required

**Ethics approval(s)**

Approved 01/02/2021, Faculty of Medicine, Damascus University (Damascus, Damascus, 1, Syria; Telephone number not provided; not@provided), ref: RS 19843,2021

**Study design**

Observational cross-sectional study

**Primary study design**

Observational

## **Secondary study design**

Cross sectional study

## **Study setting(s)**

Community

## **Study type(s)**

Other

## **Participant information sheet**

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

## **Health condition(s) or problem(s) studied**

Rheumatologic diseases

## **Interventions**

A prospective, observational study was conducted in the Eye, Ear, and Nose Surgical Hospital from June 2020 to June 2023 on 300 adult patients with rheumatic disease.

Demographic data and history regarding the disease were recorded. Ophthalmic examinations included visual acuity, slit lamp examination, dry eye tests, dilated fundus examination, and intraocular pressure.

## **Intervention Type**

Other

## **Primary outcome measure**

1. Demographic data measured using a web survey at a single timepoint
2. Medical history regarding the disease diagnosed measured using a web survey at a single timepoint
3. Symptoms measured using a web survey at a single timepoint
4. Duration of the disease measured using a web survey at a single timepoint
5. Personal history measured using a web survey at a single timepoint
6. Family history of any systemic disease or other disease measured using a web survey at a single timepoint
7. Ocular symptoms measured using a web survey at a single timepoint

## **Secondary outcome measures**

There are no secondary outcome measures

## **Overall study start date**

01/06/2020

## **Completion date**

01/06/2023

## **Eligibility**

**Key inclusion criteria**

1. All patients with diagnosed rheumatic disease based on the diagnostic criteria, classified according to the International Classification of Disease, tenth edition (ICD-10)
2. Patients with ocular symptoms who presented to the Ophthalmology department, suspicious of connective tissue disease based on history and clinical examination, whose diagnosis was confirmed by the Rheumatology department

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

34 Years

**Upper age limit**

62 Years

**Sex**

Both

**Target number of participants**

1020

**Total final enrolment**

300

**Key exclusion criteria**

Ocular symptoms due to some other cause, pre-existing ocular disease, or comorbid illness like diabetes

**Date of first enrolment**

01/06/2021

**Date of final enrolment**

01/05/2023

**Locations****Countries of recruitment**

Syria

**Study participating centre**

**Damascus University**

Damascus

Syria

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# Sponsor information

## Organisation

Damascus University

## Sponsor details

Damascus

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Syria

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## Sponsor type

University/education

## Website

<http://www.damascusuniversity.edu.sy>

# Funder(s)

## Funder type

Other

## Funder Name

Investigator initiated and funded

# Results and Publications

## Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

## Intention to publish date

01/06/2024

## Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study will be published as a supplement to the results publication

## IPD sharing plan summary

Published as a supplement to the results publication