

Ocular manifestations in rheumatologic diseases in adults

Submission date 23/08/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 27/09/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 27/09/2023	Condition category 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

Contact information

Type(s)

Scientific

Contact name

Dr Diaa Haj Ali

ORCID ID

<https://orcid.org/0000-0003-3543-5795>

Contact details

Damascus

Damascus

Syria

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+963 (0)941558285

diaaali907@gmail.com

Additional identifiers**Clinical Trials Information System (CTIS)**

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Other

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(s)

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

Key secondary outcome(s)

There are no secondary outcome measures

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

34 years

Upper age limit

62 years

Sex

All

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

Funder(s)**Funder type**

Other

Funder Name

Investigator initiated and funded

Results and Publications**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