ISRCTN41794974 https://doi.org/10.1186/ISRCTN41794974

Ocular manifestations in rheumatologic diseases in adults

Submission date
23/08/2023

Recruitment status
No longer recruiting

Registration date
27/09/2023

Overall study status
Completed

Last Edited
27/09/2023

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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 Diaa 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
1
+963 (0)941558285
diaaali907@gmail.com

Additional identifiers

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

Primary study design
Observational

Study design
Observational cross-sectional study

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
1

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