

Stratified medicine in primary Sjogren's syndrome

Submission date 31/07/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 08/08/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 05/09/2023	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

Primary Sjögren's syndrome (PSS) is a chronic, complex immune-mediated disease with no effective treatment available. The effects vary greatly among PSS sufferers with some reporting disabling fatigue, some unbearable pain and dryness, while others report fewer symptoms. Some PSS patients develop lymphoma or major extra-glandular organ damage while some have disease confined to the exocrine glands. Although many biological abnormalities have been described in PSS, their relationships with specific clinical manifestations remain unclear. This creates challenges in finding appropriate ways of measuring the effectiveness of therapies and the burden of disease. Using detailed clinical data from 600 PSS patients from the UK, researchers have identified four clinical PSS subtypes which differ in characteristics. The data suggest that outcome and response to therapies may differ depending on the patient's subtype. The aim of this study is to develop a PSS-specific patient-reported questionnaire that captures the disease burden/impact in each of the PSS subtypes.

Who can participate?

Patients aged 18 years and over with PSS and clinicians across Sweden, Norway and France

What does the study involve?

Completing questionnaires about quality of life and disease impact at baseline and follow-up.

What are the possible benefits and risks of participating?

There are no direct benefits and no risks of taking part.

Where is the study run from?

Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

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

January 2019 to October 2024

Who is funding the study?

European Commission

Who is the main contact?
Professor Wan-Fai Ng, wan-fai.ng@newcastle.ac.uk

Contact information

Type(s)

Principal investigator

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

264215

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

IRAS 264215, CPMS 48622

Study information

Scientific Title

Stratified medicine in primary Sjogren's syndrome: a mixed methods quantitative/qualitative study to develop a patient-reported questionnaire looking at disease burden within the Primary Sjogren's Syndrome subtypes

Acronym

FOREUM

Study objectives

This study aims to further characterise the clinical significance and the underpinning pathotypes of the 4 primary Sjogren's syndrome (PSS) subtypes. The researchers will develop a patient questionnaire that enables them to quantitatively measure the impact and disease burden of PSS within the different subtypes.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 09/04/2021, East of England - Cambridge East Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, United Kingdom; +44 (0)2071048096; cambridgeeast.rec@hra.nhs.uk), ref: 21/EE/0069

Study design

Observational multicentre mixed methods study

Primary study design

Observational

Study type(s)

Other

Health condition(s) or problem(s) studied

Primary Sjogren's Syndrome

Interventions

The aim of the study is to collect information on the disease impact and burden of PSS on patients. This information will be collected using questionnaires due to the large cohort (600 participants) across numerous countries. Patient public involvement is crucial to the design of the study. Patient representatives from each country are involved in the steering committee with the clinicians and will work together to develop the questionnaire.

The main categories of the questionnaire were decided at an initial face-to-face meeting with clinicians, academics, statisticians and patient representatives. These categories form the phases of the questionnaire development. The four phases will be discussed in more detail to establish questions suitable to collect the data for the categories. These discussions will take place by teleconference between the patient representatives, chief investigator, health economist and project manager.

Opinions on the draft questionnaire will first be sought from PSS patient support groups in Norway, Sweden, France and the UK. The completed questionnaire will then be submitted to REC for approval and piloted first in the UK. This will then be enrolled out to the other EU sites (Norway, Sweden and France) to complete the subtype data collection (600 participants, 150 in each subgroup).

Baseline data will be collected and a follow-up questionnaire administered. Questionnaires will be posted or given in clinic to complete at home. The timing of the follow-up will depend on the questions of interest identified for the categories during the development process. Questionnaire development and recruitment will take place over a period of two years to allow one year for data analysis.

Participants will be identified from established PSS registries across the centres. The participants of these registries have already consented to receive future invitations for PSS research. A letter of invitation, patient information sheet and written consent form will be posted to the patient or given during clinic by the clinical research team. If the participant consents then the questionnaire will be posted to them.

Intervention Type

Other

Primary outcome(s)

The following data is collected through a one off questionnaire by post.

1. Quality of life measured using EQ5D
2. Wellbeing measured using ICECAPA
3. Anxiety and depression measured using HADs
4. Sjogren's symptoms measured using ESSPRI
5. Fatigue is measured using PROFAD
6. Patient developed measure to include to include; Clinical Health Services (primary and secondary), extra services not covered by the health service – such as cost of prescriptions, dental, opticians, and alternative therapies, employment, family life and activities – such as holidays.

Key secondary outcome(s)

There are no secondary outcome measures

Completion date

31/10/2024

Eligibility

Key inclusion criteria

1. Age ≥ 18 years
2. Confirmed diagnosis of primary Sjögren's syndrome
3. Willing and able to provide informed written consent
4. Registered within a PSS registry

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Unable to provide written consent

Date of first enrolment

01/03/2021

Date of final enrolment

31/10/2023

Locations

Countries of recruitment

United Kingdom

England

France

Norway

Sweden

Study participating centre

The Newcastle upon Tyne Hospitals NHS Foundation Trust

Freeman Hospital

Freeman Road

High Heaton

Newcastle upon Tyne

United Kingdom

NE7 7DN

Sponsor information

Organisation

Newcastle upon Tyne Hospitals NHS Foundation Trust

ROR

<https://ror.org/05p40t847>

Funder(s)

Funder type

Other

Funder Name

European Commission

Alternative Name(s)

European Union, Comisión Europea, Europäische Kommission, EU-Kommissionen, Euroopa Komisjoni, EC, EU

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study will be available upon request from Victoria Macrae (victoria.macrae@newcastle.ac.uk)

IPD sharing plan summary

Available on request