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Stratified medicine in primary Sjogren's syndrome

Submission date	Recruitment status	[ ] Prospectively registered
31/07/2023	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
08/08/2023	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
05/09/2023	Musculoskeletal Diseases	[ ] 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

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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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes