

RESULT: REgistry of Sjögren syndrome in UMCG: a LongiTudinal study

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Introduction: Primary Sjögren's syndrome (pSS) is characterized by sicca symptoms of the eyes and mouth and systemic symptoms such as disabling fatigue. The disease has large impact on daily activities and quality of life. The heterogeneity of the pSS population is very large. A multidisciplinary approach is essential for optimal care of patients with pSS. The REgistry of Sjögren syndrome in Umcg – LongiTudinal (RESULT) cohort will combine up-to-date quality of care with gathering long-term prospective follow-up data in a large cohort of patients.

Objective: Primary: To identify biomarkers and clinical parameters that determine and predict the longitudinal course of pSS, taking into account patient-reported, functional, imaging, histopathological, laboratory and genetic data. Secondary: A) To identify biomarkers and parameters that determine and predict the progression from early pSS to established pSS. B) To evaluate the effect of treatment of pSS in routine clinical practice and to identify predictors of response to treatment. C) To assess the diagnostic ability of salivary gland ultrasound in pSS and its applicability in monitoring disease activity and progression.

Study design: Longitudinal observational prospective cohort study.

Study population: All consecutive patients with confirmed or probable pSS who visit the outpatient clinic of the department of Rheumatology and Clinical Immunology in the UMCG are considered for this study. Inclusion period will be 5 years (expected inclusion of ± 500 patients) and all patients will be followed up for 10 years.

Main study parameters: Clinical and patient-reported parameters, salivary and tear gland function, ultrasound and histopathology of salivary glands, laboratory parameters, immunological parameters in serum, saliva and tears, and genetic markers