

PROTOCOL/analysis plan: Work disability in newly diagnosed patients with primary Sjögren's syndrome

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Objectives:

The aim of this longitudinal population-based study is to assess Work Disability (WD), i.e. the extent of sick leave (SL) and receipt of a disability pension (DP) before and after having been diagnosed with pSS according to the American-European Classification Group (AECG) criteria. Moreover, we want to study predictors of WD in pSS patients.

METHODS

Using the population-based patient register in Malmö with Sjögren Syndrome patients between Jan 2001 and Dec 2012 receiving first diagnose. We then link data to the payment register by the Swedish Social Insurance Agency and calculate the proportion on sick leave in 30-day-intervals from 12 months before treatment start until 24 months after. For each SS patient we randomly selected 4 subjects from the general population matched for age, sex, area of residence, and date of work disability.

Types of outcome measures

The primary outcome will be changes in mean fraction of period prevalence of any sick leave or disability pension among first time diagnosed SS patients (incident cases) and general population 12 month prior to treatment compared to 24 months after.

Secondary outcome measures will be changes in Net work disability (days per month – 30 day period) prior and after treatment as well as changes changes in any sick leave split according MRI imaging positivity.

The completeness of data varies depending on the final selection of the patients eligible for cross-linkage.

Data extraction and management

TM will extract the data from registry, LEK will do the relevant cross-linkage and marking of subjects eligible for the study. Further statistical analysis will be done by TM and LEK.

Patients aged 18 to 62 years with active SS receiving their first diagnosis during the period 2001 thru 2012 and registered in the population register of the Skane region were extracted from the SS-register as eligible for cross-linkage. Likewise a reference population (general, SS) was included as described under the methods section.

The fraction (mean) of days (split according to sick leave or disability pension) with any work disability during 30-day periods (with 95% CI) 360 days prior to diagnosis and 720 days after for both SS patients and the reference population are the primary outcome. Inferential statistics regarding relative risks and analysis for trends will also be done.

Subsequently we will split data according to baseline characteristics (serology etc) – These analyses are preferable, as they yield important complementary information.

We will also calculate the *net* amount of time (as a mean fraction of 100% working time (or total days per 30 days interval) the SS patients and the matched populations were work disabled (either sick leave or disability) during 30-day intervals in the observed period.

Results:

Table 1 Baseline charac

Table 2: relative risks at different time points

Table 3: Predictor analysis

Figure 1: Total WD split according to SL/DP and pSS/GPC

Figure 2: Net days out of 30 split according to SL/DP and pSS/GPC