

Biopsychosocial characteristics of patients with fibromyalgia / chronic widespread pain. A cross-sectional review of depersonalized data from the German Pain e-Registry. (F-type Pain)

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Study

Finalised

Administrative details

PURI

<https://redirect.ema.europa.eu/resource/44366>

EU PAS number

EUPAS44365

Study ID

44366

DARWIN EU® study

No

Study countries

Germany

Study description

Fibromyalgia (FM), respective the chronic widespread pain syndrome (CWSP) is a medical condition characterized by chronic widespread pain and a heightened pain response to pressure. Other symptoms include tiredness to a degree that normal activities are affected, sleep problems, and cognitive dysfunctions. Some people also report restless legs syndrome, bowel or bladder problems, numbness and tingling and sensitivity to noise, lights or temperature. Patients with fibromyalgia are more likely to suffer from depression, anxiety and posttraumatic stress disorder. To gain further insight into the prevalence and biopsychosocial consequences of FM in patients we evaluated anonymized real-world data derived from routine medical care in pain centers within the German Pain e-Registry (GPeR), a national web-based registry developed in cooperation with the German Pain Association (Deutsche Gesellschaft für Schmerzmedizin) and the German Pain League (Deutsche Schmerzliga).

Study status

Finalised

Research institutions and networks

Institutions

[Institute for Neurological Sciences \(IFNAP\)](#)

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Contact details

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Primary lead investigator

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Study timelines

Date when funding contract was signed

Planned: 08/10/2021

Actual: 08/10/2021

Study start date

Planned: 11/10/2021

Actual: 11/10/2021

Data analysis start date

Planned: 18/10/2021

Actual: 18/10/2021

Date of final study report

Planned: 22/11/2021

Actual: 22/11/2021

Sources of funding

- Other

More details on funding

German Pain Association, IFNAP - private Institute of Neurological Sciences

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Other

Study topic, other:

Disease/Epidemiology study

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Data collection methods:

Secondary use of data

Main study objective:

To assess the extend of the biopsychosocial burden in patients with FM/CWSP

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Fibromyalgia

Population studied

Short description of the study population

Anonymized real-world data of patients derived from routine medical care in pain centers within the German Pain e-Registry (GPeR), a national web-based registry developed in cooperation with the German Pain Association (Deutsche Gesellschaft für Schmerzmedizin) and the German Pain League (Deutsche Schmerzliga).

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Special population of interest

Other

Special population of interest, other

Fibromyalgia

Estimated number of subjects

15000

Study design details

Data analysis plan

Biometric analyses will be performed using the descriptive procedures suitable for the respective data format. Mean data will be presented with standard deviation or 95% confidence intervals (CI), proportions expressed in percent (%) and if necessary, adjusted for the number of patients with available data (a%).

For statistical between subcohort comparisons Pearson's chi-square test and Wilcoxon's signed rank test will be performed using a two-sided significance level of 0.05. All comparisons will be exploratory, therefore neither significance levels will be adjusted for multiplicity nor confirmatory analyses performed. All analyses will be conducted with PASW Statistics version 18.

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

German Pain e-Registry

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No