Incidence rates of morphoea, systemic sclerosis and scleroderma

First published: 11/01/2023

Last updated: 23/04/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/50511

EU PAS number

EUPAS50510

Study ID

50511

DARWIN EU® study

No

Study countries

- ☐ France
- ☐ Germany
- ☐ Italy

Romania

Study description

This was a cohort study describing population- and patient-level incidence rates of morphoea (including localised and linear scleroderma), systemic sclerosis and scleroderma (including both systemic and localised/linear in a number of European databases. The study population was patients visiting general practices in Germany, France, Italy and Romania

Study status

Finalised

Research institutions and networks

Institutions

European Medicines Agency (EMA)

First published: 01/02/2024

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Institution

Contact details

Study institution contact

Karin Hedenmalm

Study contact

karin.hedenmalm@ema.europa.eu

Primary lead investigator

Karin Hedenmalm

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 26/09/2022

Actual: 26/09/2022

Study start date

Planned: 26/09/2022

Actual: 26/09/2022

Date of final study report

Planned: 16/12/2022

Actual: 20/12/2022

Sources of funding

- EMA

Study protocol

Final analysis plan - morphoea - 20221021.pdf(1.11 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Data collection methods:

Secondary use of data

Main study objective:

The objectives of the study were to describe: Incidence rates of (a) morphoea (including localised and linear scleroderma), (b) systemic sclerosis, and (c) scleroderma (including both systemic and localised/linear) in the general

population and in patients with diagnosis of Hodgkin lymphoma and malignant neoplasms.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Morphoea

Systemic scleroderma

Scleroderma

Population studied

Short description of the study population

The study focused on general population in the UK and patients visiting general practices in Germany, France, Spain, Italy and Romania identified from the IMRD databases to determine the incidence rates of morphoea, systemic sclerosis and scleroderma.

Age groups

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

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

Patients with morphoea, systemic sclerosis and scleroderma

Estimated number of subjects

1600

Study design details

Outcomes

Morphoea (localised and linear scleroderma), systemic sclerosis and scleroderma (including both systemic and localised/linear), Incidence rates in the general population were stratified by sex, age group, and year of recorded diagnosis. Incidence rates in patients with cancer diagnosis were stratified by sex and age

Data analysis plan

This was a cohort study describing population- and patient-level incidence rates of morphoea (including localised and linear scleroderma), systemic sclerosis and scleroderma (including both systemic and localised/linear in a number of

European databases

Documents

Study results

Final-REPORT-Nov 2022_Morphoea.pdf(738.59 KB)

Data management

Data sources

Data source(s)

IQVIA Disease Analyzer Germany

THIN® (The Health Improvement Network®)

Disease Analyzer - OMOP

IQVIA Medical Research Data - OMOP

Data sources (types)

Electronic healthcare records (EHR)

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