Long-term International Dual-Source Endometriosis and Adenomyosis Registry (LIDEA Registry)

First published: 27/10/2023

Last updated: 27/05/2024

Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/107378

EU PAS number

EUPAS107377

Study ID

107378

DARWIN EU® study

No

Study countries

☐ France

- [ ] Germany
- [ ] Italy
- [ ] Spain
- [ ] United Kingdom
- [ ] United States

Study description

This prospective registry focuses on people with a confirmed, or presumed diagnosis of the two common chronic gynecological diseases: endometriosis and adenomyosis. Longitudinal data will be collected from eligible study participants directly with the aim to better understand the course of endometriosis and adenomyosis. Specific focus will be applied to pelvic pain and quality of life outcomes under different treatment pathways as prescribed by health care practitioners in real-world clinical practice. The data collected for this registry will further contribute to knowledge generation and accelerate scientific innovation in the scientific community of endometriosis and adenomyosis.

Study status

Planned

Research institutions and networks

Institutions

Berlin Center for Epidemiology & Health Research, ZEG Berlin

- [ ] Germany

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Last updated: 20/06/2024

Institution | Laboratory/Research/Testing facility | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Klaas Heinemann

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 08/11/2022

Study start date

Planned: 31/01/2024

Date of final study report

Planned: 29/12/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Organon LLC

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 type:

Non-interventional study

Main study objective:

Epidemiological assessment of the course of pelvic pain and the development of endometriosis and/or adenomyosis./Examine treatment pathways and outcomes of pelvic pain with or without specific diagnoses (e.g. endometriosis, adenomyosis) including health economic outcomes./Examine the relationship

between changes in patient-reported outcome (PRO) measures and healthcare resources utilization.

Study Design

Non-interventional study design

Other

Population studied

Age groups

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)

Estimated number of subjects

14000

Study design details

Outcomes

See above, Effect of therapies on pain/Effect of therapies on bleeding/Identification of therapeutic gaps/Situational analysis of treatment across geographies and countries/Operative vs. medical treatment/National

preferences regarding diagnostic and therapeutic pathways, physician perception of successful disease management/Impact of disease and different treatments on work, partnership etc.

Data analysis plan

ZEG Berlin will develop a written Statistical Analysis Plan (SAP) covering the annual progress reporting according to the Study Protocol. A draft SAP including TLFs (tables, listings, figures) will be provided by ZEG Berlin to the Scientific Governance Board for review within 6 months of the study start. The SAP will describe the analysis variable derivation and statistical methodology of planned study reports.

Data management

Data sources

Data sources (types)

Disease registry

Other

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