Association between exposure to esomeprazole/omeprazole and risk of sexual dysfunction in men

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Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/1000000242

EU PAS number

EUPAS1000000242

Study ID

1000000242

DARWIN EU® study

No

Study countries

☐ Germany

United Kingdom

Study description

A cohort study which will investigate a potentially increased risk of sexual dysfunction (SD) among male patients prescribed esomeprazole/omeprazole when compared to: (a) being prescribed alternative treatments from the same drug class (i.e., other proton pump inhibitors, PPIs); (b) being prescribed alternative treatments from another drug class (i.e., histamine type 2 receptor antagonists (H2RAs)); and (c) not being prescribed PPIs or H2RAs despite indications for them (non-initiators).

Study status

Finalised

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Maria Clara Restrepo Mendez

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 03/03/2024

Actual: 10/04/2024

Study start date

Planned: 22/03/2024

Actual: 26/04/2024

Date of final study report

Planned: 15/08/2024

Actual: 30/08/2024

Study protocol

FINAL_study_protocol_Esomeprazole and sexual dysfunction_v3.2_FOR PUBLICATION.pdf(626.37 KB)

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:

Human medicinal product

Study type:

Non-interventional study

Data collection methods:

Secondary use of data

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

ESOMEPRAZOLE MAGNESIUM TRIHYDRATE

OMEPRAZOLE

Anatomical Therapeutic Chemical (ATC) code

(A02BC01) omeprazole

omeprazole

(A02BC05) esomeprazole

esomeprazole

Medical condition to be studied

Sexual dysfunction

Documents

Study report

FINAL_study_report_Esomeprazol and sexual dysfunction_v1.3_REDACTED.pdf

(2.13 MB)

Data management

Data source(s)

IQVIA Disease Analyzer Germany

IQVIA Medical Research Data - OMOP

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

No