

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

**First published:** 05/07/2024

**Last updated:** 18/10/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS1000000242

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### Study ID

1000000242

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### DARWIN EU® study

No

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### Study countries



Germany



United Kingdom

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### 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).

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### **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

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**Study start date**

Planned: 22/03/2024

Actual: 26/04/2024

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**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

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

Not applicable

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Human medicinal product

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**Study type:**

Non-interventional study

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**Data collection methods:**

Secondary use of data

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## Study drug and medical condition

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

ESOMEPRAZOLE MAGNESIUM TRIHYDRATE

OMEPRAZOLE

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**Anatomical Therapeutic Chemical (ATC) code**

(A02BC01) omeprazole

omeprazole

(A02BC05) esomeprazole

esomeprazole

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**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

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

## Data sources

### 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

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### Check completeness

Yes

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### Check stability

Yes

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### Check logical consistency

Yes

## Data characterisation

## **Data characterisation conducted**

No