DARWIN EU® - Eye disorders in women with breast cancer treated with anastrozole, letrozole or tamoxifen

First published: 26/05/2025

Last updated: 08/10/2025





Administrative details

EU PAS number	
EUPAS1000000599	
Study ID	
100000599	
DARWIN EU® study	
Yes	
Yes Study countries	
Study countries	
Study countries Croatia	

United Kingdom		

Study description

This study aims to describe the incidence of ocular adverse events after the use of anastrozole, letrozole or tamoxifen treatments in pre- and postmenopausal women with breast cancer across several European countries.

Study status

Finalised

Research institutions and networks

Institutions

Department of Medical Informatics - Health Data Science, Erasmus Medical Center (ErasmusMC)
☐ Netherlands
First published: 03/11/2022
Last updated: 02/05/2024
Institution Educational Institution ENCePP partner

Networks

Data Analysis and Real World Interrogation	Network
(DARWIN EU®)	
☐ Belgium	

Croatia
Denmark
Estonia
Finland
France
☐ Germany
☐ Greece
☐ Hungary
Italy
☐ Netherlands
□ Norway
Portugal
Spain
Sweden
United Kingdom
First published: 01/02/2024
Last updated: 30/04/2025
Network

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Anton Barchuk

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 22/01/2025

Actual: 22/01/2025

Study start date

Planned: 15/05/2025

Actual: 15/05/2025

Date of final study report

Planned: 19/09/2025

Actual: 11/09/2025

Sources of funding

EMA

Study protocol

DARWIN EU_Protocol_P3-C1-024_Eyes disorders in post-meno tted with anastrozole_V4.pdf (1.64 MB)

Regulatory



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

Study design:

A new drugs user cohort study will be conducted to assess the incidence rates of eye disorders (primary objective), pre-specified patient-level characteristics (secondary objective 1) and median time to onset of the outcome (secondary objective 2).

Main study objective:

1. To calculate incidence rates and cumulative incidence of eye disorders, overall and stratified by eye disorder (Cataract, Degeneration of retina, Keratitis, Macular hole, Retinal artery occlusion, Retinal detachment, Retinal

haemorrhage, Retinal tear, Retinal vascular disorder, Uveitis, Visual impairment, Vitreomacular traction syndrome and all visual system disorders combined), age category and type of therapy (anastrozole, letrozole or tamoxifen), among pre- and postmenopausal women with breast cancer (primary objective).

- 2. To characterise postmenopausal women with breast cancer treated with anastrozole, letrozole or tamoxifen at the start of treatment in terms of demographics and potential risk factors for eye disorders (secondary objective).
- 3. To estimate the time from initiation of anastrozole, letrozole or tamoxifen to first eye disorder (overall) among postmenopausal women with breast cancer (secondary objective).

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(L02BG03) anastrozole

anastrozole

(L02BG04) letrozole

letrozole

(L02BA01) tamoxifen

tamoxifen

Medical condition to be studied

Eye disorder

Population studied

Short description of the study population

The source population will include women aged 18 years and above with a primary diagnosis of breast cancer in the period between 01/01/2010 and 31/12/2022.

Age groups

- Adults (18 to < 65 years)
 - Adults (18 to < 46 years)
 - Adults (46 to < 65 years)
- Elderly (≥ 65 years)
 - Adults (65 to < 75 years)
 - Adults (75 to < 85 years)
 - Adults (85 years and over)

Documents

Study report

DARWIN EU_Report_P3-C1-024_Eyes disorders in post-meno tted with anastrozole V4.pdf (3.32 MB)

Data management

ENCePP Seal

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)

BIFAP - Base de Datos para la Investigación Farmacoepidemiológica en el Ámbito Público (Pharmacoepidemiological Research Database for Public Health Systems)

Clinical Practice Research Datalink (CPRD) GOLD

Hospital District of Helsinki and Uusimaa patient cohort (FinOMOP)

IQVIA Disease Analyzer Germany

Croatia National Public Health Information System (Nacionalni javnozdravstveni informacijski sustav)

Data sources (types)

Disease registry

Electronic healthcare records (EHR)

Use of a Common Data Model (CDM)

CDM mapping

Yes

CDM Mappings

CDM name

OMOP

CDM website

https://www.ohdsi.org/Data-standardization/

CDM version

https://ohdsi.github.io/CommonDataModel/index.html

Data quality specifications

Unknown Check completeness Unknown

Check stability

Check conformance

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No