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

First published: 26/05/2025

Last updated: 03/06/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000599

Study ID

1000000599

DARWIN EU® study

Yes

Study countries

- [ ] Croatia
- [ ] Finland
- [ ] Germany
- [ ] Spain

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

Ongoing

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

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

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

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

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)

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)

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

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No