DARWIN EU® - Suicidality incidence rates in adult male patients and in patients treated with finasteride and dutasteride

First published: 19/12/2024

Last updated: 27/05/2025

Study Finalised

Administrative details

EU PAS number

EUPAS1000000423

Study ID

1000000423

DARWIN EU® study

Yes

Study countries

- [ ] Croatia
- [ ] Denmark
- [ ] Germany
- [ ] Netherlands

☐ Spain

☐ United Kingdom

Study description

Finasteride is a specific inhibitor of 5α-reductase, an enzyme that converts testosterone into dihydrotestosterone. It is approved in Europe for treating benign prostatic hyperplasia (BPH) at 5 mg and androgenetic alopecia at 1 mg and 2.275 mg/dl.

Dutasteride, another 5α-reductase inhibitor, is also approved in Europe for moderate-to-severe BPH, either alone or in combination with tamsulosin.

In some non-EEA countries, dutasteride is also prescribed for androgenetic alopecia.

Signals of mood changes, including depressed mood, depression, and rarely suicidal ideation, have been reported in patients using finasteride.

Depression is listed as a side effect of finasteride, along with anxiety and suicidal thoughts, though their frequency is unknown.

These psychiatric effects were not identified during clinical trials but were later explored in post-marketing observational studies. There is insufficient data in the literature regarding the incidence rates of suicide related events in these populations.

The aim of this study is to evaluate the incidence rates of suicide-related events in adult male patients exposed to finasteride or dutasteride medicines for the conditions of androgenetic alopecia and BPH.

Having incidence rate data would be helpful to contextualise and to give some insight into the impact of the indication on suicide-related events. Further understanding of the safety of these medicines regarding their potential psychiatric effects can help inform regulatory decisions and the assessment of the benefit/risk profile of these medicines.

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

Marzyeh Amini

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 14/10/2024

Actual: 14/10/2024

Study start date

Planned: 04/12/2024

Actual: 04/12/2024

Date of final study report
Planned: 31/01/2025

Actual: 14/02/2025

Sources of funding

- EMA

Study protocol

DARWIN EU_Protocol_P3-C1-019_Finasteride and Suicide_V5.pdf(1.28 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

Scope of the study:

Disease epidemiology

Data collection methods:

Secondary use of data

Study design:

Population-Level Cohort

Main study objective:

The specific objectives are to describe overall incidence rates of suicide-related events and stratified by age group, history of psychiatric disorder, history of sexual dysfunction, and calendar year (for the general adult male population) and follow-up year (for indication and treatment cohorts) in:

1. The general adult male population.
2. Adult male patients with newly diagnosed androgenetic alopecia.
3. Adult male patients with newly diagnosed androgenetic alopecia initiating treatment for this condition (finasteride, dutasteride, topical minoxidil, and non-treated with prescribed study treatments).
4. Adult male patients with newly diagnosed benign prostatic hyperplasia (BPH).
5. Adult male patients with newly diagnosed BPH initiating treatment for this condition (finasteride, dutasteride, alpha blockers, tadalafil, and non-treated with prescribed study treatments).

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

FINASTERIDE

Anatomical Therapeutic Chemical (ATC) code

(D11AX10) finasteride

finasteride

(G04CB02) dutasteride

dutasteride

Medical condition to be studied

Androgenetic alopecia

Benign prostatic hyperplasia

Population studied

Short description of the study population

The study population will include all adult male patients (≥ 18 years old) present in the data source during the study period (Objective 1).
Within this population 2 sub-cohorts will be nested namely one of adult male patients newly diagnosed with androgenetic alopecia and one consisting of adult male patients newly diagnosed with BPH (Objectives 2 and 4).
Within these cohorts of adult males newly diagnosed with androgenetic alopecia and BPH, we will nest cohorts of individuals initiating treatments of interest for the first time in the study period (Objectives 3 and 5).

Documents

Study report

DARWIN EU_Report_P3_C1-019_Finasteride_V4.0.pdf(5.44 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)

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

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

Danish Health Data Registries

InGef Research Database

Integrated Primary Care Information (IPCI)

The Information System for Research in Primary Care (SIDIAP)

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

Unknown