

# Suicide and suicidality after exposure to finasteride (Suicidality with finasteride)

**First published:** 03/04/2020

**Last updated:** 28/06/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS34531

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### Study ID

34598

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### DARWIN EU® study

No

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### Study countries

 United Kingdom

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### Study description

This study was discontinued during the COVID-pandemic, therefore marked as 'finalised' -

Finasteride - indicated for benign prostatic hyperplasia (BPH) and male pattern

hair loss (MPHL) - is known to cause psychiatric side effects. There are ongoing signals of persistence of psychiatric events after discontinuation of finasteride and of suicide/self-injury which remain under close monitoring. The principal objectives of this study are: (i) to assess the extent to which patients prescribed finasteride 5mg (BPH indication) are at increased risk of recorded suicide and suicide-related outcomes compared with patient prescribed alternative treatments for BPH, (ii) to assess if any association between finasteride 5mg exposure and recorded suicidality persists after cessation of therapy, and (iii) to describe the pattern of recorded events in patients prescribed finasteride 1mg (MPHL indication). This will be a cohort study with cohorts defined based on patients' exposure to the medicines under investigation. The population eligible for the study will consist of male patients (finasteride is not indicated for use in females) registered with an IMRD-UK registered GP-practice for a duration of one-year or more. To avoid potential confounding relating to differing baseline risks a covariate adjusted analysis will be used. This will require the use of a minimum one-year lookback period prior to the start of follow-up to establish any baseline comorbidities. The primary analysis will be a new-user "inception" cohort of patients established through the one-year screening period to define incident use. Patients will be followed from the date of first prescription until an event or censored. The primary (composite) analysis will follow-up until first event and the secondary (component part / alternative composite) analysis will follow-up until first event of each type. Patients will be censored at the end of follow-up or when they switch to alternative therapy for BPH.

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## **Study status**

Finalised

## Research institutions and networks

### Institutions

# European Medicines Agency (EMA)

**First published:** 01/02/2024

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Institution

## Contact details

### Study institution contact

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Study contact

[robert.flynn@ema.europa.eu](mailto:robert.flynn@ema.europa.eu)

### Primary lead investigator

Flynn Robert

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 01/02/2020

Actual: 01/02/2020

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### Study start date

Planned: 01/02/2020

Actual: 01/02/2020

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**Data analysis start date**

Planned: 01/04/2020

Actual: 01/04/2020

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**Date of final study report**

Planned: 30/06/2020

Actual: 30/06/2020

## Sources of funding

- Other

## More details on funding

Internally EMA funded study

## Study protocol

[Brief protocol - suicidality with finasteride v2 20200402\\_clean.pdf](#) (268.31 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 type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

**Main study objective:**

To assess if use of finasteride is associated with increased risk of suicidality.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Anatomical Therapeutic Chemical (ATC) code**

(D11AX01) minoxidil

minoxidil

(D11AX10) finasteride

finasteride

(G04CA) Alpha-adrenoreceptor antagonists

Alpha-adrenoreceptor antagonists

(G04CA51) alfuzosin and finasteride

alfuzosin and finasteride

(G04CA52) tamsulosin and dutasteride

tamsulosin and dutasteride

(G04CB01) finasteride

finasteride

(G04CB02) dutasteride

dutasteride

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### **Medical condition to be studied**

Suicidal ideation

## Population studied

### **Age groups**

- Adolescents (12 to < 18 years)
  - Adults (18 to < 46 years)
  - Adults (46 to < 65 years)
  - Adults (65 to < 75 years)
  - Adults (75 to < 85 years)
  - Adults (85 years and over)
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### **Estimated number of subjects**

200000

## Study design details

### **Outcomes**

The primary outcome will be a composite consisting of the first occurrence of any of the following events: completed suicide, attempted suicide, and suicidal ideation. The secondary outcomes will be the component parts of the primary outcome, following up until the first event of each of the following: (i) completed suicide, (ii) completed or attempted suicide. In addition, all-cause

deaths will be used as a sensitivity analysis because of the risk of misclassification of cause of death.

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### **Data analysis plan**

Multivariable survival modelling (most likely a Cox proportional hazards model) will be used to calculate adjusted Hazard Ratios associated with medication of interest use vs comparators, adjusting for potential confounders measured at baseline. Covariates will be included in the analysis by contributing to a propensity score for each patient and will be included in the model as inverse probability of treatment weights.

## 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)**

THIN® (The Health Improvement Network®)

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### **Data sources (types)**

[Electronic healthcare records \(EHR\)](#)

## Use of a Common Data Model (CDM)

## **CDM mapping**

No

## Data quality specifications

### **Check conformance**

Unknown

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

No