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

Study ID

34598

DARWIN EU® study

No

Study countries

☐ United Kingdom

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.

Study status

Finalised

Research institutions and networks

Institutions

European Medicines Agency (EMA)

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Flynn Robert

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/02/2020

Actual: 01/02/2020

Study start date

Planned: 01/02/2020

Actual: 01/02/2020

Data analysis start date
Planned: 01/04/2020

Actual: 01/04/2020

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

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

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

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

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)

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.

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®)

Data sources (types)

Electronic healthcare records (EHR)

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No