Finasteride and male breast cancer – a register-based nested case-control study in Denmark, Finland, Norway, and Sweden (MK-0906-162)

First published: 04/05/2017

Last updated: 11/04/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/25923

EU PAS number

EUPAS17620

Study ID

25923

DARWIN EU® study

No

Study countries

- [ ] Denmark
- [ ] Finland
- [ ] Norway
- [ ] Sweden

Study description

The objective of this study is to investigate the potential association between finasteride (MK-0906) exposure and the development of breast cancer in men residing in Denmark, Sweden, Finland, and Norway from data in national registries. The primary hypothesis of this study is that the previously reported increased incidence of male breast cancer among finasteride users is explained by confounding factors.

Study status

Finalised

Research institutions and networks

Institutions

Department of Epidemiology, Institute of Applied Economics and Health Research (ApHER)

- [ ] Denmark

First published: 22/02/2013

Last updated: 01/07/2019

Institution | EU Institution/Body/Agency | ENCePP partner

Contact details

Study institution contact

Clinical Trials Disclosure Merck Sharp & Dohme Corp.

Study contact

ClinicalTrialsDisclosure@merck.com

Primary lead investigator

Anders Green

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 01/05/2011

Study start date

Actual: 01/05/2011

Data analysis start date

Planned: 30/11/2017

Actual: 30/11/2017

Date of final study report

Planned: 30/06/2018

Actual: 02/05/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Merck Sharp & Dohme Corp.

Study protocol

0906-162 protocol_final-redaction.pdf(9.64 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Other study registration identification numbers and links

Study number: MK-0906-162NCT number: NCT01703520

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Secondary use of data

Main study objective:

1. To describe finasteride users compared to non-users with respect to potential confounding factors.2. To analyze the effect of finasteride use on male breast cancer incidence while takingaccount of confounding factors that may explain the previously reported increasedincidence.

Study Design

Non-interventional study design

Case-control

Study drug and medical condition

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

FINASTERIDE

Medical condition to be studied

Breast cancer male

Population studied

Short description of the study population

Males residing in either Denmark, Finland, Norway, or Sweden on the index date who were aged 35 years and older.
In substudy 1: Finasteride user group included men who have redeemed at least two prescriptions of finasteride in the study period (either as one group or divided into three groups, i.e. 2-3 packs of 98 pills, 4-6 packs, and 7+ packs), and Non-finasteride user group included men who have redeemed less than two prescriptions of finasteride in the study period.
In substudy 2: Men with a diagnosis of primary breast cancer (see section 9.2.3 Primary breast cancer case definition) were included as cases, whereas men without a diagnosis of breast cancer at index date were included as controls.

Age groups

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)

Special population of interest

Other

Special population of interest, other

Breast cancer male patients

Estimated number of subjects

428000

Study design details

Outcomes

Stage 1 - Person-Years of Exposure to Finasteride by Participant Age and Year
Stage 1 - Initial Incidence Rates of Male Breast Cancer Stratified by Exposure to FinasterideStage 1 - All-Cause Mortality Rates in Males with Breast Cancer by Exposure to FinasterideStage 2 - Odds (or Likelihood) of Exposure to Finasteride in Male Breast Cancer Cases Relative to Controls

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Data analysis plan

1. Logistic regression will be performed by comparing potential confounding factors forfinasteride users compared to non-users and between levels of cumulative finasteride use. 2. Conditional logistic regression will be performed by comparing male breast cancercases with controls in respect to either finasteride users versus non-users or cumulative finasteride use and including confounding factors in the analysis.

Documents

Study results

p162mk0906-interim-final-report_Final Redaction .pdf(4.43 MB)

Study report

0906-P162-annex-1_Final Redaction.pdf(8.12 MB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Nation-wide registers with information on prescription drugs, cancer incidence,hospital discharges, and occupation were used. Information from representative surveys on lifestyle factors were also included.

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

Unknown