Association between the Prevalence of cardiovascular risk factors and new use of testosterone

First published: 29/03/2018

Last updated: 01/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS23347

Study ID

29773

DARWIN EU® study

No

Study countries

United Kingdom

Study status

Finalised

Research institutions and networks

Institutions

Institute for Epidemiology, Statistics and Informatics

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Institution

Contact details

Study institution contact

Carlos Martinez carlos.martinez@pharmaepi.com

Study contact

carlos.martinez@pharmaepi.com

Primary lead investigator

Carlos Martinez

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 13/04/2017

Study start date

Planned: 01/04/2018

Actual: 01/04/2018

Date of final study report
Planned: 31/05/2018

Actual: 14/06/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bayer AG

Study protocol

BATES01 - 0.6 - Protocol_Final_geschwärzt.pdf (427.47 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

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

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

To investigate if testosterone is preferentially given to patients at higher risk profile for cardiovascular events.

Study Design

Non-interventional study design

Case-control

Study drug and medical condition

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

TESTOSTERONE

Anatomical Therapeutic Chemical (ATC) code

(G03BA03) testosterone

testosterone

Medical condition to be studied

Hypogonadism male

Population studied

Short description of the study population

All male individuals aged 18 years or older in the source population with a first testosterone use during the study period.

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)

Estimated number of subjects

23000

Study design details

Outcomes

Estimation of the association between cardiovascular risk factors and initiation of testosterone therapy

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Data analysis plan

The study uses a case-control design. Cases will be ascertained using product and Read medical codes indicating testosterone use. Up to five controls will be drawn from the source population for each case, matched on year of birth, history of pathological hypogonadism (primary or secondary) and GP consultation ±30 days of the index day of the respective case. Descriptive statistics of demographic and baseline clinical characteristics on the index day will be presented for cases and matched controls, including lifestyle factors, pathological hypogonadism (primary or secondary), symptoms associated with hypogonadism, comorbidities, comedications and cardiovascular (CV) risk factors. Crude and adjusted odds ratios (OR) with 95% confidence intervals of the association between CV factors and initiation of testosterone therapy will be estimated using conditional logistic regression for matched case-control data. Results will be stratified by history of pathological hypogonadism.

Documents

Study results

19547_EU-PAS_Abstract_2019-05-13_Redacted.pdf (128.24 KB)

Study report

19547_study report_EU PAS Register_Redacted.pdf (635.93 KB)

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)

Clinical Practice Research Datalink

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

Unknown