The Risk of Venous Thrombotic Events among Males Treated with Testosterone Replacement Therapy (I5E-MC-B003)

First published: 02/10/2013

Last updated: 26/04/2016

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/13309

EU PAS number

EUPAS4894

Study ID

13309

DARWIN EU® study

No

Study countries

☐ United States

Study description

Primary Objective: To evaluate the VTE risk using cohort study design by estimating the incidence rates (IRs), and hazard ratio (HR) of VTE among hypogonadal patients treated with testosterone replacement therapy (overall and by different routes of administration) relative to a propensity score matched untreated comparison groupSecondary Objective: To evaluate the VTE risk using a nested case-control study within original cohort by estimating the crude and adjusted odds ratio (OR) of VTE for patients exposed to testosterone products (overall and by different routes of administration) compared to untreated hypogonadal patientsStudy design: A retrospective cohort study is proposed as a primary study design, with a nested case-control study as a secondary study design. The retrospective cohort observational study will use electronic claims records in the United States (US) to assess the crude and adjusted incidence rate of VTE among patients newly treated with any testosterone products relative to hypogonadal patients without testosterone treatment matched on baseline characteristics and calendar time. A nested case-control study will be performed within the original hypogonadal cohort.

Study status

Finalised

Research institutions and networks

Institutions

Eli Lilly and Company

First published: 01/02/2024

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Hu Li

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 04/10/2013

Actual: 15/02/2013

Study start date

Planned: 04/02/2014

Actual: 04/03/2014

Data analysis start date

Planned: 01/04/2014

Actual: 29/05/2014

Date of final study report

Planned: 30/09/2014

Actual: 23/10/2014

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly and Company

Study protocol

Axiron VTE study protocol_final Oc0413_submitted Enepp Feb 2014.pdf(302.97 KB)

Regulatory

Was the study required by a regulatory body?

No

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

To evaluate the VTE risk using cohort study design by estimating the incidence rates (IRs), and hazard ratio (HR) of VTE among patients treated with testosterone replacement therapy (overall and by different routes of administration) relative to a propensity score matched untreated comparison group.

Study Design

Non-interventional study design

Cohort

Case-control

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(G03BA03) testosterone

testosterone

Medical condition to be studied

Venous thrombosis

Population studied

Short description of the study population

Male Hypogonadal patients aged 18 years or old with at least 12 months (365 days) of continuous enrollment in the health plan prior to the index date.

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

Hypogonadal patients

Estimated number of subjects

3229

Study design details

Outcomes

According to the suggestion of FDA Mini-sentinel project, the following ICD-9 codes are used to define VTE : 415.x, 451.x, and 453.x. Three physicians will be adjundicating the claims of each case and dertermine if it is a idiopathic or non-idiopathic VTE case.

Data analysis plan

Please provide a brief summary of the analysis method: The primary analysis of this protocol is to compare the percentage of patients who developed incident VTE after index date in treated patients who received at least 1 prescription of any testosterone products versus untreated patients who have not received any testosterone prescription. Propensity score matching method will be applied to select untreated cohort and match to treated cohort. Cox regression model will be used to estimate the incidence rate and hazard ratio. For the secondary (nested case-control) analysis, the conditional logistic regression is planned for univariate and multivariate analyses. The association between testosterone exposure patterns (current and past exposure of testosterone) will be reported as crude and adjusted OR representing the testosterone exposures relative to non-testosterone users.

Documents

Study publications

Li H, Benoit K, Wang W, Motsko S. Association between use of exogenous testoste…

Data management

Data sources

Data source(s), other

Marketscan THAM United States

Data sources (types)

Administrative healthcare records (e.g., claims)

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