Testosterone Replacement Therapy (TRT) and Risk of Acute Myocardial Infarction (AMI): An Administrative Healthcare Claims Study (F1D-MC-B006)

First published: 31/03/2015

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Study   Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/13304

EU PAS number

EUPAS9151

Study ID

13304

DARWIN EU® study

No

Study countries

☐ United States

Study description

Several recent studies reported a higher risk of acute myocardial infarction (AMI) in patients treated with TRT. However, these studies were inconclusive due to concerns over the study design. Thus, the association between TRT and AMI risk is not clearly understood. This study proposes to investigate whether there is an association between TRT and AMI. Specifically the objectives are as following:Primary objective: To evaluate the incidence of AMI among patients treated with TRT relative to propensity score matched untreated hypogonal patients.Secondary objectives: To evaluate the incidence of AMI among patients treated with TRT relative to propensity score matched PDE5i treated patients.

Study status

Finalised

Contact details

Study institution contact

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Primary lead investigator

Hu Li

(Primary lead investigator)

Study timelines

Date when funding contract was signed

Planned: 15/04/2015

Actual: 15/04/2015

Study start date

Planned: 16/04/2015

Actual: 16/04/2015

Date of final study report

Planned: 29/01/2016

Actual: 31/03/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly and Company

Study protocol

B006 PASS.pdf(1.85 MB)

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:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Secondary use of data

Main study objective:

Primary objective: To evaluate the incidence of AMI among patients treated with TRT (any testosterone prescription and major testosterone prescriptions) relative to a propensity score matched untreated hypogonal patients cohort.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

TESTOSTERONE

Medical condition to be studied

Acute myocardial infarction

Population studied

Short description of the study population

Male patients aged 18 years or older with at least 12 months (365 days) of continuous enrollment in a health plan prior to the index date and who had at least 1 prescription for testosterone products, at least 1 prescription for PDE5i, or at least 1 diagnosis of hypogonadism condition related International Classification of Diseases, Ninth Revision (ICD 9) codes.

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

10462

Study design details

Outcomes

Acute myocardial infarction

Data analysis plan

The baseline characteristics for the pre-matched population will be presented. A summary of baseline characteristics will also be presented for those subjects

who are not included in the propensity score-matched analysis. The primary analysis of this protocol is to compare AMI risk between propensity score matched TRT treated patients versus untreated patients, using a Cox proportional hazard model. The secondary comparison of the AMI risk between propensity score matched TRT-treated patients vs. PDE5i-treated patients. The following subgroup analyses will be conducted:1) TRT routes of administration (gel/topical, patch, injectable, non-specified),2) By prior cardiovascular condition (as listed in Table 9.2),3) By age group (18-64 years, ≥65 years),Additional sensitivity analysis may be performed on a post hoc basis.

Documents

Study results

Non_interventional PASS Final Study Report_11Apr2016_for encepp.pdf(1.28 MB)

Data management

Data sources

Data source(s), other

Truven Marketscan 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