EMA study on prescribing of testosterone in the primary care setting

First published: 24/06/2014

Last updated: 19/07/2016

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/14151

EU PAS number

EUPAS6827

Study ID

14151

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

At its meeting 07–10 April 2014 the Pharmacovigilance Risk Assessment Committee (PRAC) of the European Medicines Agency (EMA) started a review of testosterone-containing medicines under Article 31 of Directive 2000/83/EC. The review was triggered by concerns about possible cardiac side effects of these medicines. The safety concerns were raised following the publication of a study suggesting that the use of testosterone increases the risk of myocardial infarction (heart attack) in men aged over 65 years, as well as in younger men with pre-existing heart disease. This study followed other studies including the Veterans Health Care Study, which suggests that men with pre-existing heart disease who received treatment with testosterone had a higher risk of heart problems than men who did not receive testosterone.The present study aims to describe the extent and patterns of prescription of testosterone in a primary care setting in the European Union in line with the scope of the Article 31 referral. This will be done using the EMA’s in-house IMS Health data. The primary objective of the study is to estimate the prevalence of testosterone use in males from 1990 to Q1 2013.Furthermore new users during the study period will be stratified according to recorded indication of use as well as dosage form prescribed. For the new users, co-morbidities at the time of the initial prescription will be determined based on prescription data using a validated method.

Study status

Finalised

Research institutions and networks

Institutions

European Medicines Agency (EMA)

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Institution

Contact details

Study institution contact

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Primary lead investigator

Kristian Svendsen

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 14/04/2014

Actual: 14/04/2014

Study start date

Planned: 01/05/2014

Actual: 01/05/2014

Date of final study report

Planned: 10/06/2014

Actual: 10/06/2014

Sources of funding

- EMA

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 topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

To estimate the prevalence of testosterone use in males from 1990 to Q1 2013.

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(G03BA03) testosterone

testosterone

Population studied

Short description of the study population

All patients recorded in the UK IMS database who had received a prescription of testosterone

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

5686400

Study design details

Data analysis plan

This study is a descriptive analysis of data from IMS Health. No sample size or statistical precision calculation is performed. Data extraction and management is performed in IMS Disease Analyser, analyses are performed using Stata 11.2.

Documents

Study report

EMA_testosterone_IMS report.pdf(460.88 KB)

Data management

Data sources

Data source(s), other

IMS Disease Analyzer UK, United Kingdom

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