Trittico Prolong 300 mg in the treatment of depression

First published: 12/06/2017

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS19469

Study ID

28262

DARWIN EU® study

No

Study countries

☐ Czechia

Study status

Finalised

Research institutions and networks

Institutions

Angelini Pharma

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Institution

Multiple centres: 8 centres are involved in the study

Contact details

Study institution contact

Renata Kellnerova info@angelini.cz

Study contact

info@angelini.cz

Primary lead investigator

Renata Kellnerova

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 01/07/2015

Study start date
Actual: 08/07/2015

Date of final study report
Actual: 30/06/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Angelini Pharma Česká republika s.r.o.

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

CZ SIDC number 1505070002

Methodological aspects

Study type

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

The non-interventional questionnaire study aim was to investigate the safety and efficacy of Trittico Prolong 150 mg and Trittico Prolong 300 mg tablets in the treatment of moderate (MADRS score 21-25) to severe (MADRS scores ≥ 26) depression with single dose of 300 mg trazodone in common clinical practice.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Non-interventional post-authorization safety study

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(N06AX05) trazodone

trazodone

Medical condition to be studied

Major depression

Population studied

Short description of the study population

Depressive patients aged 18 years or older of different etiology, including those associated with anxiety, sleep disorders or sexual dysfunctions of inorganic origin. The population included both hospitalized and outpatients.

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

Major depression patients

Estimated number of subjects

85

Study design details

Outcomes

MADRS, CGI/S, CGI/I scores, nature, frequency and intensity of the adverse drug reactions.

Data analysis plan

Standard descriptive statistics (Wilcoxon test, McNemar test)

Documents

Study results

Trittico Prolong_final report_SUKL.pdf(664.1 KB)

Study publications

Češková E, Šedová M, Kellnerová R, Starobová O. Once-a-day trazodone in the tre…

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

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