# Trittico Prolong 300 mg in the treatment of depression

First published: 12/06/2017

Last updated: 02/07/2024





# Administrative details

<b>EU PAS number</b> EUPAS19469	
<b>Study ID</b> 28262	
DARWIN EU® study	
Study countries	
Czechia	

## **Study status**

**Finalised** 

Research institutions and networks

## **Institutions**

# Angelini Pharma

First published: 01/02/2024

**Last updated:** 01/02/2024

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

# **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

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