Active surveillance of overdose with a prolonged-release formulation of tramadol/paracetamol. The PICS study.

First published: 09/03/2021

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Study Ongoing

Administrative details

EU PAS number

EUPAS39805

Study ID

45995

DARWIN EU® study

No

Study countries

- [ ] Czechia
- [ ] Hungary
- [ ] Poland
- [ ] Portugal

- [ ] Romania
- [ ] Slovakia
- [ ] Slovenia

Study description

This is an observational, non-comparative, non-interventional and international, multicentre, prospective, single arm post-authorisation safety study carried out to monitor actively the safety of the product in terms of acute single intake overdose cases. Multiple clinical sites including Poison Information Centres and other designated clinical institutions will participate in countries where the product is on the market. Overdose cases will be followed during a single hospital stay of the subjects. Primary collection of data will be carried out during entire period of hospitalization. The follow up period is going to be approximately two years after the start of the study in the country with the latest start of the data collection.

Study status

Ongoing

Research institutions and networks

Institutions

University Medical Centre Ljubljana

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Institution

Department of Occupational Medicine First Faculty of Medicine, Charles University Toxicological Information Centre / 4th internal clinic, General University Hospital in Prague Prague, Czech Republic, Department of Emergency Medicine and Clinical Toxicology Budapest, Hungary, Hospital Curry Cabral – Unidade de Cuidados Intensivos Lisabon, Portugal, Childrens Hospital Grigore Alexandrescu Bucharest, Romania, II. Interna klinika SZU Dept Internal Med II.HEGITO div Hepatology, Gastroenterologty and Liver transplantation SZU slovak Medical University, FNsP F.D.Roosevelt Univ. Hospital Banska Bystrica, Slovakia, Pomeranian Center of Toxicology Gdansk, Poland

Contact details

Study institution contact

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Primary lead investigator

Miran Brvar

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 31/03/2021

Actual: 28/05/2021

Study start date

Planned: 20/06/2021

Actual: 15/07/2021

Data analysis start date

Planned: 30/08/2023

Date of interim report, if expected

Planned: 30/10/2023

Date of final study report

Planned: 31/07/2025

Sources of funding

- Pharmaceutical company and other private sector
- Other

More details on funding

Krka, d. d. Novo mesto, Contractual partner, Tecnimede

Regulatory

Was the study required by a regulatory body?

No

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

The main objective is: • to evaluate the effectiveness of risk minimisation measures in reducing the risk of hepatotoxicity after the overdose with the product

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Intensive monitoring schemes

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(N02AJ13) tramadol and paracetamol

tramadol and paracetamol

Medical condition to be studied

Toxicity to various agents

Overdose

Population studied

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

30

Study design details

Outcomes

Primary outcomes include: • Total number of overdose cases with OMP treated in our study • The ratio of cases with serious sequelae related to paracetamol poisoning, with respect to total number of cases treated in our study, The secondary outcomes encompass 27 items related with: • Demography /Vital signs/Comorbidities • Concomitant therapy including those involved in the overdose • Exposure and clinical/laboratory characteristics • Therapy characteristics • Disease outcomes

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Data analysis plan

The study is primarily descriptive and non-comparative. Qualitative data (e.g. gender, concomitant diseases, etc.) will be summarized by frequency count and percentages. Percentages will be calculated using the number of patients in the relevant population as the denominator. Quantitative data (e.g. age, body weight, blood pressure, etc.) will be summarized by appropriate descriptive statistics. Where appropriate, 95% confidence intervals will be presented. An interim analysis is planned to be carried out in this study with the interim data capture point of August 1, 2023. Data from all patients participated in this study

will be used in the analysis, due to expected small sample size, no center effect will be assessed.

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

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

No