Preventable Adverse Drug Reactions reported to the Croatian Agency for Medicinal Products and Medical Devices (PREVENTABLE)

First published: 20/11/2015

Last updated: 19/06/2024

Study Planned

Administrative details

EU PAS number

EUPAS11644

Study ID

26827

DARWIN EU® study

No

Study countries

Croatia

Study description

Non-interventional, observational study aimed at identifying, evaluating and describing preventable adverse drug reactions (ADRs) among the spontaneously reported ADRs to the Croatian Agency for Medicinal Products and Medical Devices (HALMED) will be conducted. Estimated total number of reports included in the study is 1000 cases and will capture individual case safety reports (ICSR) in the period between 2013 and 2015. The previously validated “P-method” will be employed to systematically detect preventable ADRs in ICSR sent to the Croatian pharmacovigilance centre at HALMED.

Study status

Planned

Research institutions and networks

Institutions

Department for Pharmacovigilance and Rational Pharmacotherapy, Agency for Medicinal Products and Medical Devices (Phv Department -HALMED)

Croatia

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Institution **Regulatory Authority** **ENCePP partner**

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Nikica Mirošević Skvrce

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/01/2015

Study start date

Planned: 01/01/2005

Data analysis start date

Planned: 01/01/2015

Date of final study report

Planned: 31/12/2016

Sources of funding

- Other

More details on funding

HALMED

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

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 objective of the study is to identify, evaluate and describe preventable adverse drug reactions among the spontaneously reported ADRs to the Croatian Agency for Medicinal Products and Medical Devices (HALMED).

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Descriptive study

Population studied

Age groups

- Preterm newborn infants (0 – 27 days)
- Term newborn infants (0 – 27 days)
- Infants and toddlers (28 days – 23 months)
- Children (2 to < 12 years)
- 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)

Special population of interest

Hepatic impaired

Immunocompromised

Pregnant women

Renal impaired

Estimated number of subjects

1000

Study design details

Outcomes

To identify the proportion of preventable adverse drug reactions (ADRs) among the spontaneously reported ADRs.To describe the preventable ADRs in terms of seriousness, pertaining SOC, ATC classification, number of drugs used, setting in which ADR occurred, indication for use of suspected drug, and category according to p-method. To identify risk factors contributing to preventable ADR occurrence

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Data analysis plan

Descriptive study. The previously validated “P-method” will be employed to systematically detect preventable ADRs in individual case safety reports (ICSR) sent to the Croatian pharmacovigilance centre (PVC) at HALMED.

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)

Spontaneous reports of suspected adverse drug reactions

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