Incidence and outcome of paracetamol poisoning

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Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/17369

EU PAS number

EUPAS6420

Study ID

17369

DARWIN EU® study

No

Study countries

☐ Sweden

Study description

During the past few years there has been a rapid increase in the number of exposure calls to the Swedish national poison center regarding paracetamol poisoning. The number of calls is probably an underestimation of the true incidence of this type of poisoning. The national hospital discharge registry is considered to have questionable reliability for estimation of incidence of this type of poisoning due to a large and increasing proportion of poisonings given an entirely unspecific ICD-10 code (T51.9 without ATC-code).The aim of the planned study is to collect individual data on actual levels of S-Paracetamol from hospital laboratories nation-wide. Cases will be defined by the S-paracetamol level, thus circumventing the problem with unspecific hospital discharge coding of poisonings. Based on this case definition information will be linked from the Swedish hospital discharge registry, Cause of death registry, and the Swedish prescribed drug register to target the following main goals:• Estimate annual incidence and change over time during the last 10 years.• By time series analysis evaluate possible effects of previous regulatory interventions, e.g. when sales of paracetamol was allowed outside pharmacies.• Describe outcome of this type of poisoning.• Estimate reliability of incidence based on data sources such as frequency of exposure calls to poison center.• Develop and validate indicators and time series analyses based on such data to be able to evaluate effects of future regulatory action.

Study status

Finalised

Research institutions and networks

Institutions

Medical Products Agency

Contact details

Study institution contact

Rolf Gedeborg

Study contact

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Primary lead investigator

Rolf Gedeborg

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 01/01/2014

Study start date

Planned: 05/05/2014

Actual: 09/05/2014

Data analysis start date

Planned: 01/09/2014

Actual: 03/11/2014

Date of final study report

Planned: 15/12/2014

Actual: 16/01/2017

Sources of funding

- Other

More details on funding

Medical Products Agency

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 topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Data collection methods:

Secondary use of data

Main study objective:

Estimate incidence and outcome of paracetamol poisoning

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

PARACETAMOL

Medical condition to be studied

Poisoning deliberate

Accidental poisoning

Liver disorder

Death

Population studied

Short description of the study population

Patients admitted to hospitals in Sweden for paracetamol poisoning identified from hospital discharge diagnoses and cause of death in national health-care databases.

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

Estimated number of subjects

50000

Study design details

Outcomes

- Impact of intervention on monthly count of poisoning events (interrupted time series analysis), - Health care utilisation- Liver failure- Liver transplant- Death

Data analysis plan

- Incidence estimation- Time series analysis

Documents

Study results

Gedeborg_et_al-2017-Pharmacoepidemiology_and_Drug_Safety.pdf(899.85 KB)

Data management

Data sources

Data source(s)

Sweden National Prescribed Drugs Register / Läkemedelsregistret

Data source(s), other

Hospital laboratory data Sweden, National patient register Sweden, Cause of death register Sweden

Data sources (types)

Disease registry

Drug dispensing/prescription data

Other

Data sources (types), other

Prospective patient-based data collection, The main data source is individual laboratory results (S-paracetamol) collected from hospital laboratories and linked to other data sources.

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