

# Incidence and outcome of paracetamol poisoning

**First published:** 28/04/2014

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Study

Finalised

## Administrative details

### EU PAS number

EUPAS6420

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### Study ID

17369

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### DARWIN EU® study

No

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### Study countries

 Sweden

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### 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.

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### **Study status**

Finalised

## Research institutions and networks

### Institutions

[Medical Products Agency](#)

## Contact details

### **Study institution contact**

Rolf Gedeborg rolf.gedeborg@mpa.se

Study contact

[rolf.gedeborg@mpa.se](mailto:rolf.gedeborg@mpa.se)

### **Primary lead investigator**

Rolf Gedeborg

Primary lead investigator

## Study timelines

### **Date when funding contract was signed**

Actual: 01/01/2014

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### **Study start date**

Planned: 05/05/2014

Actual: 09/05/2014

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### **Data analysis start date**

Planned: 01/09/2014

Actual: 03/11/2014

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### **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

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### **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

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#### **Study type:**

Non-interventional study

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#### **Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

**Data collection methods:**

Secondary use of data

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**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

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**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.

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### **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)
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### **Special population of interest**

Hepatic impaired

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### **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

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### **Data analysis plan**

- Incidence estimation- Time series analysis

## Documents

## Study results

[Gedeborg\\_et\\_al-2017-Pharmacoepidemiology\\_and\\_Drug\\_Safety.pdf](#) (899.85 KB)

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## 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 source(s)

Sweden National Prescribed Drugs Register / Läkemedelsregistret

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### Data source(s), other

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

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### Data sources (types)

[Disease registry](#)

[Drug dispensing/prescription data](#)

[Other](#)

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### 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

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

Unknown