Prescribing of paracetamol in patients with chronic renal failure A Drug Utilisation Study (Paracetamol doses in renal failure)

First published: 03/04/2020

Last updated: 30/01/2025

Study Finalised

Administrative details

EU PAS number

EUPAS34516

Study ID

34517

DARWIN EU® study

No

Study countries

Germany

United Kingdom

Study description

Paracetamol doses were studied in patients with and without renal failure.

Study status

Finalised

Research institutions and networks

Institutions

European Medicines Agency (EMA)

First published: 01/02/2024

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Robert Flynn

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 04/04/2019

Actual: 04/04/2019

Study start date
Planned: 03/05/2019

Actual: 03/05/2019

Date of final study report
Planned: 17/07/2019

Actual: 17/07/2019

Sources of funding

- EMA

Regulatory

Was the study required by a regulatory body?

Yes

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:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

To compare doses of paracetamol in patients with and patients without renal failure.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Observational study

Study drug and medical condition

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

PARACETAMOL

Medical condition to be studied

Renal failure

Population studied

Short description of the study population

Patients aged 45 years or older diagnosed with chronic renal failure received treatment with paracetamol identified from the IMRD database of UK, France and Germany.

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

Renal impaired

Estimated number of subjects

1.200.000

Study design details

Data analysis plan

Descriptive analysis.

Documents

Study results

Paracetamol doses_renal failure_results_final.pdf (1.89 MB)

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)

THIN® (The Health Improvement Network®)

Data sources (types)

Electronic healthcare records (EHR)

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