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: 02/04/2024

Study | Finalised

Administrative details

PURI
https://redirect.ema.europa.eu/resource/34517

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 institution and networks

Institutions

European Medicines Agency (EMA)

First published: 01/02/2024
Last updated 01/02/2024

Institution

Contact details

Study institution contact
Robert Flynn

Study contact

robert.flynn@ema.europa.eu
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 data collection

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
1200000

Study design details

Data analysis plan
Descriptive analysis.

Documents

Study results
Paracetamol doses_renal failure_results_final.pdf(1.89 MB)

Data management

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