A drug utilisation study of Rifaxamin-α 550mg

First published: 07/06/2017

Last updated: 01/04/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/28600

EU PAS number

EUPAS19445

Study ID

28600

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

A drug utilisation study conducted in CPRD GOLD to understand the dosing, the formulation, the indications and the patient demographics associated with rifaximin-α 550mg tablets across the UK following launch in January 2013.

Study status

Finalised

Research institutions and networks

Institutions

Clinical Practice Research Datalink (CPRD)

United Kingdom

First published: 15/03/2010

Last updated: 17/01/2025

Institution | Laboratory/Research/Testing facility | ENCePP partner

Contact details

Study institution contact

Bharat Amlani

Study contact

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Primary lead investigator

Jennifer Campbell

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 16/12/2014

Actual: 18/12/2014

Study start date
Planned: 21/04/2015

Actual: 06/07/2016

Date of final study report
Planned: 09/07/2015

Actual: 18/01/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Norgine Ltd

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

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 determine the characteristics of patients in the UK prescribed Rifaxamin 550mg and to gain understanding of the risk associated with use of Rifaxamin 550mg and paediatric use, off-label use and drug-drug interactions

Study drug and medical condition

Name of medicine, other

Targaxan

Population studied

Short description of the study population

Patients in the UK who were prescribed Rifaxamin 550mg.

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

400

Study design details

Data analysis plan

The drug utilisation study will characterise the dosing, formulation, the indications and the patient demographics associated with rifaxamin 550mg tablets across the UK following launch in January 2013. Tables of descriptive data (including counts, mean, median, standard deviation and interquartile range) on each patient cohort will be presented.

Data management

Data sources

Data source(s)

Clinical Practice Research Datalink

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

Unknown