A description of the UK NHS hospital resource use and patient quality of life associated with hospitalisations for recurrent Clostridium difficile infection

First published: 25/04/2014

Last updated: 25/04/2014

Study Ongoing

Administrative details

EU PAS number

EUPAS6413

Study ID

6414

DARWIN EU® study

No

Study countries

United Kingdom

Study description

A multi-centre, non-interventional study to describe UK hospital resource use and quality of life (QoL) associated with hospitalisations for recurrent Clostridium difficile infection (CDI). Primary objective: to describe the cost of hospital resource use of patients with a CDI recurrence. Secondary objectives: to determine the number of days hospitalised for CDI recurrence, the cost of hospital resource between CDI episodes and to describe QoL of patients hospitalised for CDI. The study has two parts: 1) Retrospective collection of clinical/resource use data from medical records of patients who have had a first CDI episode and are hospitalised with a recurrence within 12 weeks of end of treatment of first episode (cases) or have not had a recurrence within 12 weeks (matched controls). 2) Prospective assessment of health-related QoL of patients hospitalised for CDI, through patient-completion of the EQ5D-3L questionnaire, with recording of demographic details from medical records.

Study status

Ongoing

Research institutions and networks

Institutions

Merck Sharp & Dohme LLC

United States

First published: 01/02/2024

Last updated: 08/07/2025

Institution **Pharmaceutical company**

Royal Free Hospital

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Leeds General Infirmary Leeds, UK, The Royal Free Hospital London, UK, Glasgow Royal Infirmary Glasgow, UK, Royal Sussex County Hospital Brighton, UK, Sunderland Royal Hospital Sunderland, UK, Manchester Royal Infirmary Manchester, UK

Contact details

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Primary lead investigator

Mark Wilcox

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 13/11/2012

Study start date
Actual: 23/09/2013

Data analysis start date
Planned: 30/06/2014

Date of final study report
Planned: 31/08/2014

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.

Regulatory

Was the study required by a regulatory body?

No

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Main study objective:

To describe the cost of hospital resource use of patients with a recurrence of CDI

Study Design

Non-interventional study design

Case-control

Study drug and medical condition

Medical condition to be studied

Clostridium difficile infection

Population studied

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)

Estimated number of subjects

180

Study design details

Outcomes

Difference in total hospital resource (£) (including prescribing, infection control measures, diagnostic tests, supplementary nutrition, multidisciplinary team review, stay per ward/side room) between patients with and without recurrent CDI hospitalisation and stratified for patients with a mild/moderate recurrence of CDI and for those with a severe recurrence of CDI. Difference in no. days hospitalised between patients with (cases) and without (controls) CDI recurrence, stratified by severity of recurrence, total hospital resource (£) for the period between first and recurrent CDI, stratified by severity of recurrence, mean EQ5D score for patients with CDI hospitalisations, overall and stratified by age/disease severity, patient/disease characteristics.

Data analysis plan

This study is designed to be descriptive of recurrent CDI overall and not to detect differences between different treatment regimens for CDI, although descriptive sub-group analyses will be conducted according to patient and disease characteristics. Both distributions and descriptive statistics of both central tendency (medians and arithmetic or geometric means) and dispersion (standard deviation, interquartile range) will be presented for quantitative variables. Nominal variables will be described with frequencies, percentages and modes, while ordinal variables will also have medians and interquartile ranges described.

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 sources (types)

Other

Data sources (types), other

Prospective patient-based data collection, Retrospective data collection from patients’ routine hospital medical records

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