ISRCTN61977500 https://doi.org/10.1186/ISRCTN61977500

To understand the impact of rifaximin on the NHS hospital resource use associated with the management of patients with hepatic encephalopathy (HE)

Submission date
12/08/2014

Recruitment status
No longer recruiting

Registration date
29/08/2014

Overall study status
Completed

Last Edited
19/05/2017

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Hepatic encephalopathy (HE) is a nervous system-related mental disorder for which symptoms include level of consciousness, slowing down of thoughts and movements, deterioration of mental status, confusion, and, in severe forms, coma. HE is a common complication of chronic liver cirrhosis caused by abnormal levels of toxins that accumulate in the blood, which are normally excreted in a healthy liver. We are carrying out a clinical study to understand the effect of a drug called rifaximin in treating patients with HE and how rifaximin is used in the management of HE in routine UK clinical practice.

Who can participate?
Patients who have been diagnosed with HE and are not taking rifaximin and patients on rifaximin for at least 12 months before the start of the study.

What does the study involve?
Details of all recorded inpatient (including critical care) and A&E episodes will be obtained for all patients, for the full 12-month periods before and after starting on rifaximin, even if rifaximin was discontinued prior to 12 months.

What are the possible benefits and risks of participating?
There is no additional risk to patients from taking part in this study since it only involves a retrospective review by a researcher of their medical records and electronic hospital admissions data.

Where is the study run from?
The study is run from tsecondary/tertiary care centres in the follwoing areas of the UK: Belfast, Bristol, Cambridge, Dundee, Durham, Edinburgh, Glasgow, Kings, Liverpool, Newcastle, Nottingham, Portsmouth, Royal Free, Southampton, Truro.

When is the study starting and how long is it expected to run for?
July 2013 to September 2016

Who is funding the study?
Norgine Ltd, UK (UK)

Who is the main contact?
1. Mr Robert Dew (public)
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2. Dr Sharmila Kar (scientific)
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
ZZ2013UK01

Study information

Scientific Title
The impact of rifaximin on the NHS hospital resource use associated with the management of patients with hepatic encephalopathy (HE): a retrospective observational study

Acronym
IMPRESS

Study objectives
Clinical trial data have demonstrated the potential of rifaximin to reduce overt hepatic encephalopathy (HE) episodes and hospitalisations. There is therefore a need by physicians, commissioners and other healthcare professionals caring for people with HE to understand the impact of management with rifaximin on NHS resource use in real world clinical practice. Currently available data is from evaluations undertaken in single UK centres. The study also aims to describe the characteristics of patients currently being managed with rifaximin and the associated patient pathways. It is hoped that these data will provide valuable information for physicians and commissioners to assist decision making and facilitate effective service provision and patient management in the NHS both acutely and long-term.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West of Scotland, REC 3, 20/06/2014, ref. 14/WS/1017

Study design
Non-interventional multi-centre retrospective observational research study

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Hepatic encephalopathy

Interventions
This study will involve a review of the secondary/tertiary care medical records and electronic hospital admissions data for patients with hepatic encephalopathy who have received rifaximin as part of normal clinical practice. Patients initiated on rifaximin will be identified by members of the routine care team from hospital pharmacy databases with 6 months pre- vs post-initiation of rifaximin (liver specific). Data is collected from medical records and will be recorded and collected for the period of 12 months pre- and post-initiation of rifaximin.

Intervention Type
Other

Phase

Not Applicable

Primary outcome measure
Data collection for the 6 months pre- vs post-initiation of rifaximin (liver-specific), including number of hospital bed days per patient.

Secondary outcome measures
1. Comparison of resource use: 6 months pre- vs post-initiation of rifaximin (liver specific and all cause) mainly evaluating hospitalisation (and re-hospitalisation) rates and hospital length of stay including ITU/HDU admissions
2. Patients' demographics and disease-related characteristics
3. Patient pathway
4. Adverse drug reactions to rifaximin

Overall study start date
11/07/2013

Completion date
09/09/2016

Eligibility

Key inclusion criteria
1. Patients with a clinical diagnosis of hepatic encephalopathy
2. Hepatic encephalopathy diagnosed prior to initiation of rifaximin
3. Patients initiated on rifaximin for hepatic encephalopathy at least 12 months prior to the date of data collection
4. Both female and male, no restriction of age

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants
250-300 patients

Key exclusion criteria
1. Patients receiving rifaximin where subsequent clinical diagnosis excludes hepatic encephalopathy
2. Patients initiated on rifaximin at hospitals not taking part in the study
3. Patients for whom hospital records are unavailable

Date of first enrolment
12/08/2014

Date of final enrolment
24/06/2015

Locations

Countries of recruitment
England

Northern Ireland

Scotland

United Kingdom

Study participating centre
Freeman Hospital
Freeman Road
Newcastle upon Tyne
United Kingdom
NE7 7DN

Study participating centre
Queen Alexandra Hospital
Southwick Hill Road
Portsmouth
United Kingdom
PO6 3LY

Study participating centre
Queen's Medical Centre
Derby Road
Nottingham
United Kingdom
NG7 2UH

Study participating centre
Royal Free Hospital
Pond Street
London
United Kingdom
NW3 2QG

Study participating centre
Royal Liverpool University Hospital
Prescot Street
Liverpool
United Kingdom
L7 8XP

Study participating centre
King's College Hospital
Denmark Hill
London
United Kingdom
SE5 9RS

Study participating centre
Royal Cornwall Hospital
Penventinnie Lane
Truro
United Kingdom
TR1 3LQ

Study participating centre
Addenbrooke's Hospital
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Study participating centre
Southampton General Hospital
Tremona Road
Southampton
United Kingdom
SO16 6YD

Study participating centre
Southmead Hospital
Southmead Road

Bristol
United Kingdom
BS10 5NB

Study participating centre
Ninewells Hospital
Ninewells Avenue
Dundee
United Kingdom
DD2 1UB

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Royal Victoria Hospital
Grosvenor Road
Belfast
United Kingdom
BT12 6BA

Study participating centre
University Hospital of North Durham
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DH1 5TW

Sponsor information

Organisation
Norgine Ltd (UK)

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Sponsor type
Industry

ROR
https://ror.org/046zgtw08

Funder(s)

Funder type
Industry

Funder Name
Norgine Ltd (UK)

Results and Publications

Publication and dissemination plan
Planned publication in a peer reviewed journal.

Intention to publish date
01/04/2017

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2017		Yes	No
HRA research summary			28/06/2023	No	No