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Patient and family experience of the clinical-care pathway for teduglutide in patients with short bowel syndrome and type 3 intestinal failure

Submission date
12/04/2019

Recruitment status
No longer recruiting

Registration date
29/04/2019

Overall study status
Completed

Last Edited
06/06/2023

Condition category
Digestive System

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

Plain English summary of protocol

Background and study aims
Patients with short bowel syndrome and type three intestinal failure cannot absorb sufficient nutrition from food via the intestines and are dependent on artificial feeding given directly into the vein. Teduglutide has been licensed for use in these patients and may reduce their requirements for parenteral nutrition (teduglutide is an analogue of human glucagon-like peptide-2 [GLP-2], which preserves mucosal integrity by promoting growth and repair of the intestine). Although patients taking the drug are routinely monitored via a strict clinical pathway at a specialist intestinal failure unit, there has been little research into the patient and family experience of complying with the pathway and of taking the drug.

Who can participate?
To be eligible patients must be over 18 years of age, treated at Salford Royal hospital, have short bowel syndrome, suitable for teduglutide, and dependent on parenteral nutrition at least twice a week.

What does the study involve?
Each patient will be asked to nominate a family member involved in their care to take part. Patients will inject themselves with teduglutide and be monitored weekly by the healthcare team. Patients will be interviewed at baseline and four times during the treatment about their experiences. Patients will be asked to take photographs to showing their life on parenteral nutrition and the transition back to normal food. They will also be asked to draw or indicate on a map where they go and connections they have with other people. Patients will also complete questionnaires indicating their health related quality of life. Their nutritional status and body composition will be measured by height, weight, bioelectrical impedance, hand grip strength, food diaries and activity levels. Family members or friends taking part will be interviewed three times during the treatment to find out how changes in the patients nutrition and clinical monitoring is affecting them.

What are the possible benefits and risks of participating?
The possible benefit is that some patients have found that they can reduce volume of total parenteral nutrition (TPN) they need or they have reduced the number of nights that they need to take TPN. Patients have reported that reducing the number of nights they need TPN has improved their quality of life.

Taking part in the study involves close monitoring and clinic visits. In addition, some people have side effects from teduglutide. These include gastrointestinal symptoms, heart problems, anxiety, respiratory infections and influenza-like illness, fluid balance problems, headaches and insomnia. There is also an increased risk of gastrointestinal cancer on the drug. However, whilst on the study participants will be closely monitored.

Where is the study run from?
Salford Royal Hospital, Manchester, UK

When is the study starting and how long is it expected to run for?
May 2019 to March 2023

Who is funding the study?
Funding provided by Shire Pharmaceuticals

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number
NHS001478

Study information

Scientific Title
Patient and family experience of the pathway for glucagon-like peptide 2 analogue

Study objectives
To determine if a clinical care pathway for teduglutide (glucagon-like peptide 2 [GLP-2] analogue) is practical and offers benefits for patients and their families

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved11/04/2019, East of England - Cambridgeshire and Hertfordshire Research Ethics Committee (Fiedlder Centre, Hatfield Business Park, Hatfield Avenue, Hatfield, AL10 9TP; 02071048035; nrescommittee.eastofengland-cambsandherts@nhs.net), ref:19/EE/0062

Study design
Single-centre longitudinal cohort study

Primary study design
Observational

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Intestinal failure

Interventions
This is a mixed method study looking at the patient and family experience of the clinical pathway of teduglutide and how patients and families experience any transfer from parenteral nutrition to normal diet. A patient and family member will be interviewed about their experiences and these will be placed in the context of the clinical pathway and with various quantitative measures of patient health.

Qualitative interviewing has been chosen as the best method of investigating that experience. In line with a person centered approach we will use participatory mapping and photo-elicitation as triggers for the interviews.

Quantitative measures will allow the qualitative interviews to be put in a context. Patients will complete health and quality of life questionnaires: Parenteral Nutrition Impact Questionnaire, Elphs Activities of Daily living, Hospital anxiety and Depression Scale, Patient Health Questionnaire - 9, have anthropometric measures and nutritional status measures taken.

Total duration of observation: 12 months. Total duration of follow up: 12 months.

Intervention Type
Behavioural

Primary outcome(s)
The primary aim of this research is the patient and carer experience of the teduglutide pathway. This will be measured by:
1. Patient interviews taken at baseline, 6 weeks, 24 weeks and 52 weeks ±4 weeks
2. Patient questionnaires: Parenteral Nutrition Impact questionnaire, Activities of daily living questionnaire, EQ-5D-5L, Hospital and anxiety 3. and depression scale, Patient health questionnaire-9 taken at baseline, 16 weeks, 36 weeks and 52 weeks
3. 3 day food diaries taken at baseline, 16 weeks, 36 weeks and 52 weeks
4. Handgrip strength taken at baseline, 16 weeks, 36 weeks and 52 weeks
5. Bioelectrical impendence taken at baseline, 16 weeks, 36 weeks and 52 weeks
6. Family member interview at 6 weeks, 24 weeks and 52 weeks ±4 weeks

Key secondary outcome(s))
There are no secondary outcome measures.

Completion date
31/03/2023

Eligibility

Key inclusion criteria
1. Diagnosed with short bowel syndrome or intestinal failure
2. Metabolically stable,
3. Apyrexial
4. Able to give informed consent
5. Can speak English
6. Stable on PN following a period of postsurgical intestinal adaption
7. Dependent on receiving PN at least twice a week
8. Able to inject themselves with Tedugutide
9. Managed by the IFU at Salford Royal NHS Trust

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
8

Key exclusion criteria
1. Under 18 years of age
2. Not suitable for Teduglutide:
2.1 Pregnant or planning conception in the next 12 months
2.2 History of malignancies within the last five years
2.3 Severe hepatic or renal impairment
3. Clinically unstable concomitant diseases: cardiovascular, respiratory, renal, infectious, endocrine, hepatic, or central nervous system.

Date of first enrolment
05/06/2019

Date of final enrolment
30/06/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Salford Royal NHS Trust
Stott Ln
Salford
United Kingdom
M6 8HD

Sponsor information

Organisation
University of Manchester

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Industry

Funder Name
Shire

Alternative Name(s)
Shire plc

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Results and Publications

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

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		22/06/2021	06/06/2023	Yes	No
HRA research summary			28/06/2023	No	No
Plain English results			06/06/2023	No	Yes