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Influence on quality of life of various treatment choices of people with drug-resistant epilepsy

Submission date
14/08/2020

Recruitment status
No longer recruiting

Registration date
26/08/2020

Overall study status
Completed

Last Edited
19/10/2022

Condition category
Nervous System Diseases

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Epilepsy is a condition that affects the brain and causes seizures. Epilepsy surgery is recommended for people with epilepsy (PWE) whose seizures cannot be managed by antiepileptic drugs (AEDs). The aim of this study is to examine how different groups of PWE drawn from the same group of repeat emergency department (ED) attenders fare when the NICE Guideline care pathways for people with epilepsy is applied to them. PWE will be in one of four groups:
1. Those who follow the surgical pathway, including vagus nerve stimulation (VNS) treatment
2. Those who have a change of medication to 3rd generation antiepileptic medication
3. Those who have no change initially but are followed up in specialist care
4. Those who do not engage with specialist services offered
The researchers propose to look at people's quality of life in each group, including a quarterly review of medical records looking at changes to seizure frequency and type, ED attendance, tolerance, compliance and use of rescue medications.

Who can participate?
Patients aged over 18 who have attended the Royal Cornwall Hospital (Treliske) ED at least twice between 2018-2018 and have not been seen since 01/01/2019 by an epilepsy specialist

What does the study involve?
Participants complete a set of questionnaires including a quality of life questionnaire and the Connect Epilepsy tool. This will be completed at the start of the study and quarterly for 1 year after. Each participant's medical records will be accessed for ED attendance, use of rescue medications, paramedic attendance, and side effects. Each group will be offered treatments as per routine clinical practice and choice:
Group 1: PWE eligible for surgery: This group will be referred to a tertiary centre (Bristol) for suitable assessment and surgery. PWE may receive 3rd generation AEDs while their decision for surgery awaits confirmation.
Group 2: PWE either is ineligible for surgery or choose not to be referred for one. PWE undergo a second assessment for most beneficial AED. They might receive 3rd Generation AEDs.
Group 3: PWE refuses surgery and/or change in medication. This group's treatment plan does not change but continue to see epilepsy specialists.

Group 4: PWE who do receive treatment change and are unwilling to engage with specialist services. However, patient admissions to ED will be recorded.
Each group's medical records will be reviewed on a quarterly basis for the above-described data for 1 year and exit interviews are conducted.

What are the possible benefits and risks of participating?
Participants may benefit from an improvement in their quality of life.

Where is the study run from?
Royal Cornwall Hospital (Treliske) and Cornwall Partnership NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
January 2019 to September 2024

Who is funding the study?
Liva Nova Inc. (USA)

Who is the main contact?
Sarah Lennard
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
272686

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Version 2.0, IRAS 272686

Study information

Scientific Title
Pharmacoresistant epilepsy treatment options & quality of life V1

Study objectives
The aim of the study is to examine how different groups of PWE drawn from the same cohort of being repeat ED attenders fare when the NICE Guideline care pathways for people with epilepsy is applied to them. PWE will be in one of four groups:
1. Those who follow the surgical pathway, including VNS
2. Those that have a change of medication to 3rd generation antiepileptic medication
3. Those that have no change initially but are followed up in specialist care
4. Those that do not engage with specialist services offered

The researchers propose to look at people's quality of life in each group, including a quarterly review of medical records looking at changes to seizure frequency and type, ED attendance, tolerance, compliance and use of rescue medications.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/06/2020, London - Camberwell St Giles Research Ethics Committee (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK; +44 (0)2071048103; camberwellstgiles.rec@hra.nhs.uk), REC ref: 20/LO/0700

Study design
Observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Pharmacoresistant epilepsy in adults

Interventions
Stage 1: Treatment Plan
An epilepsy specialist will review an identified cohort of PWE (serial no-attenders to ED). Reviewed PWE will be divided into four groups depending on the assessor's recommendations and PWE engagement and treatment choice.

Stage 2: Pre-Treatment Questionnaire
All consenting PWE will complete a set of questionnaires before beginning their treatment and at their reviews. Information on side effects, medication effectiveness, compliance, Emergencies (ED, paramedic attendance, rescue medication), risk assessments (Sudden Unexpected Death in Epilepsy (SUDEP) & Seizure Safety Checklist) and quality of Life (QOL) scales (QOLIE-31 and Connect Epilepsy tool)

Step 3: Treatments
Each group will be offered treatments as per routine clinical practice and choice:
Group 1: PWE eligible for surgery: This group will be referred to a tertiary centre (Bristol) for suitable assessment and surgery. PWE may receive 3rd generation AEDs while their decision for surgery awaits confirmation.
Group 2: PWE either is ineligible for surgery or choose not to be referred for one. PWE undergo a second assessment for most beneficial AED. They might receive 3rd Generation AEDs.
Group 3: PWE refuses surgery and/or change in medication. This group's treatment plan does not change but continue to see epilepsy specialists.
Group 4: PWE who do receive treatment change and are unwilling to engage with specialist services. However, patient admissions to ED will be recorded.

Step 4: Follow Up
Each group's medical records will be reviewed on a quarterly basis for the above-described data collection for 1 year, QOL questionnaires will also be completed quarterly for 1 year together with exit interviews for QOL scales conducted for those in groups 1-3.

Intervention Type
Mixed

Primary outcome measure
Quality of life measured using QOLIE-31 at baseline then quarterly for 1 year

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/01/2019

Completion date
01/09/2024

Eligibility

Key inclusion criteria
Diagnosis of epilepsy

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
150

Key exclusion criteria
Unable to give consent

Date of first enrolment
31/10/2021

Date of final enrolment
30/06/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Cornwall Partnership NHS Foundation Trust
Carew House
Beacon Technology Park
Dunmere Road
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PL31 2QN

Study participating centre
Royal United Hospitals Bath
Royal Bath Hospital
Combe Park
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Study participating centre
Royal Free London
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Sponsor information

Organisation
Cornwall Partnership NHS Foundation Trust

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cpn-tr.cftresearch@nhs.net

Sponsor type
Hospital/treatment centre

Website
https://www.cornwallft.nhs.uk/

ROR
https://ror.org/0517ad239

Funder(s)

Funder type
Industry

Funder Name
Liva Nova USA Inc.

Results and Publications

Publication and dissemination plan
Current publication and dissemination plan as of 18/06/2021:
1. Planned publication of the protocol
2. Initial publication following audit due for publication by the end of 2020
3. Final results publication

Previous publication and dissemination plan:
1. Planned publication of the protocol
2. Initial publication following audit due for publication by the end of 2020

Intention to publish date
01/04/2024

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No