

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

<b>Submission date</b> 14/08/2020	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 26/08/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 19/10/2022	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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  
sarah.lennard@nhs.net

## Contact information

**Type(s)**  
Public

**Contact name**  
Mrs Sarah Lennard

**ORCID ID**  
<https://orcid.org/0000-0001-9033-6752>

**Contact details**  
The Kernow Building  
Wilson Way  
Pool  
Pool  
United Kingdom  
TR15 3QE  
+44 (0)1209 204020  
sarah.lennard@nhs.net

**Type(s)**  
Scientific

**Contact name**  
Dr Rohit Shankar

**ORCID ID**  
<https://orcid.org/0000-0002-1183-6933>

## Contact details

Carew House  
Beacon Technology Park  
Dunmere Road  
Bodmin  
United Kingdom  
PL31 2QN  
+44 (0)1208 834455  
rohit.shankar@nhs.net

## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Integrated Research Application System (IRAS)

272686

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

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

## **Study type(s)**

Quality of life

## **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(s)**

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

## **Key secondary outcome(s))**

There are no secondary outcome measures

**Completion date**

01/09/2024

## Eligibility

**Key inclusion criteria**

Diagnosis of epilepsy

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**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**

United Kingdom

England

**Study participating centre**

**Cornwall Partnership NHS Foundation Trust**

Carew House

Beacon Technology Park

Dunmere Road

Bodmin

United Kingdom

PL31 2QN

**Study participating centre**

**Royal United Hospitals Bath**  
Royal Bath Hospital  
Combe Park  
Bath  
United Kingdom  
BA1 3NG

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

## Sponsor information

**Organisation**  
Cornwall Partnership NHS Foundation Trust

**ROR**  
<https://ror.org/0517ad239>

## Funder(s)

**Funder type**  
Industry

**Funder Name**  
Liva Nova USA Inc.

## Results and Publications

### 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?
<a href="#">HRA research summary</a>			28/06/2023	No	No