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

Submission date	Recruitment status	[X] Prospectively registered
14/08/2020	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
26/08/2020	Completed	Results
Last Edited	Condition category	Individual participant data
19/10/2022	Nervous System Diseases	<ul><li>Record updated in last year</li></ul>

## 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

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## 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

#### **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 typeDetailsDate createdDate addedPeer reviewed?Patient-facing?HRA research summary28/06/2023NoNoParticipant information sheet11/11/202511/11/2025NoYes