

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	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 26/08/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 19/10/2022	Condition category 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
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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
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

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The Kernow Building
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+44 (0)1209 204020
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