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A study to look at the clinical, human and economic effects on patients who suffer prolonged epileptic seizures

Submission date
17/09/2026

Recruitment status
Recruiting

Registration date
19/11/2026

Overall study status
Ongoing

Last Edited
13/11/2026

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
The study is designed to look at patients who suffer from prolonged seizures (PS) in epilepsy. The study will collect information on the clinical effects (medical outcomes), human effects (effects on everyday life) and economic effects (effects on ability to work) in this group of patients.

Who can participate?
Patients aged at least 12 years old who suffer from PS

What does the study involve?
Patients will be asked to complete questionnaires (three times over a 6-month period) and study diaries capturing seizures for 6 months. These will be completed electronically on a phone or tablet.

What are the possible benefits and risks of participating?
There are no benefits from taking part, but the study may collect information which is useful in the treatment of this group of patients in the future.

Where is the study run from?
UCB Biopharma SRL (Belgium)

When is the study starting and how long is it expected to run for?
September 2026 to September 2027

Who is funding the study?
UCB Biopharma SRL (Belgium)

Who is the main contact?
Fiona McNulty, fiona.mcnulty@ubc.com

Contact information

Type(s)
Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
370112

Study information

Scientific Title
The clinical, humanistic and economic patient burden of prolonged seizures in epilepsy: a prospective observational study in the UK (RWE1597)

Acronym
RWE1597

Study objectives
1. To characterize the population of patients with PS in terms of demographic and clinical characteristics, including diagnostic and medical history, and seizure type(s)
2. To characterize the patient experience of PS events and clinical outcomes over the observation period

3. To describe healthcare resource utilization (HCRU) in patients with PS
4. To assess health-related quality of life (HRQoL) in patients with PS

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 25/08/2026, Proportionate Review Sub-committee of the South West - Central Bristol Research Ethics Committee (2 Redman Place Stratford, London, E20 1JQ, United Kingdom; -; centralbristol.rec@hra.nhs.uk), ref: 26/SW/0100

Primary study design
Observational

Secondary study design
Prospective observational study

Study type(s)

Health condition(s) or problem(s) studied
Epilepsy

Interventions
Observational study including questionnaires and patient diaries. Patients will receive usual care. Patients will be asked to complete questionnaires (three times over a 6-month period) and study diaries capturing seizures for 6 months. These will be completed electronically on a phone or tablet.

Intervention Type
Other

Primary outcome(s)
1. Health-related quality of life measured using the Patient-Weighted Quality of Life in Epilepsy Inventory (QOLIE-31-P) for adults or Quality of Life in Epilepsy Inventory for Adolescents (QOLIE-AD-48) for adolescents at baseline, 3 months and 6 months

2. General health status measured using the EuroQol 5-Dimensions, 5-Levels (EQ-5D-5L) or EuroQol 5-Dimensions, 5-Levels Youth version (EQ-5D-Y-5L) at baseline, 3 months and 6 months

3. Depressive symptoms measured using the Neurological Disorders Depression Inventory for Epilepsy (NDDI-E) or Neurological Disorders Depression Inventory for Epilepsy Youth (NDDI-E-Y) at baseline, 3 months and 6 months

4. Epilepsy-related stigma measured using the revised Epilepsy Stigma Scale (rESS) or Epilepsy Stigma Scale for Children at baseline and 6 months

5. Patient-reported experiences and impacts of prolonged seizures measured using non-validated questionnaires at baseline and 3 months

6. Prolonged seizure characteristics, including seizure frequency, type, duration, associated symptoms, injuries, rescue medication use, recurrence and recovery time, measured using a seizure diary at baseline and monthly from month 1 to month 6

Key secondary outcome(s)

Completion date
15/09/2027

Eligibility

Key inclusion criteria
1. Is at least 12 years old at the time of providing assent/consent for study participation
2. Has a documented medical diagnosis of epilepsy
3. Is at risk of prolonged seizures (PS) according to the REST definitions based on physician's clinical impression of seizure history and disease status
4. Has had at least one PS event within the last month prior to study enrolment evaluation
5. Patient has sufficient cognitive ability to understand the Patient-Reported Outcome questionnaires and seizure diary items and to provide their own answers. Patients may receive non-directive assistance limited to technical or physical support (e.g., typing or navigating the device), provided that all response content is generated by the patient
6. Informed consent and, where applicable, assent for participation will be obtained in accordance with applicable national regulations and the procedures approved by the Ethics Committee
7. The patient, and caregiver/LAR if applicable, has sufficient command of English language to understand the study information and requirements

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
12 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Is enrolled in any clinical trial at the time of assent/consent for study participation
2. Has a history of presence of known non-epileptic seizures which cannot be distinguished from qualifying epileptic seizures

Date of first enrolment
09/09/2026

Date of final enrolment
09/03/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
The Royal Wolverhampton NHS Trust
New Cross Hospital
Wolverhampton Road
Heath Town
Wolverhampton
England
WV10 0QP

Study participating centre
The Newcastle upon Tyne Hospitals NHS Foundation Trust
Freeman Hospital
Freeman Road
High Heaton
Newcastle upon Tyne
England
NE7 7DN

Study participating centre
Sheffield Teaching Hospitals NHS Foundation Trust
Northern General Hospital
Herries Road
Sheffield
England
S5 7AU

Study participating centre
University College London Hospitals NHS Foundation Trust
250 Euston Road
London

England
NW1 2PG

Sponsor information

Organisation
UCB

Funder(s)

Funder type

Funder Name
UCB

Alternative Name(s)
Union Chimique Belge, UCB Biopharma SRL, UCB S.A., Belgium, UCB S.A.

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Belgium

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available