

# Simultaneous Administration of Lorazepam and Levetiracetam in nonconvulsive Status Epilepticus, followed by intravenous valproate

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| <b>Submission date</b><br>12/03/2008   | <b>Recruitment status</b><br>No longer recruiting    | <input type="checkbox"/> Prospectively registered    |
| <b>Registration date</b><br>30/04/2008 | <b>Overall study status</b><br>Completed             | <input type="checkbox"/> Protocol                    |
| <b>Last Edited</b><br>19/05/2022       | <b>Condition category</b><br>Nervous System Diseases | <input type="checkbox"/> Statistical analysis plan   |
|  |  | <input checked="" type="checkbox"/> Results          |
|  |  | <input type="checkbox"/> Individual participant data |

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

Clinical Trials Information System (CTIS)  
2008-001098-13

## Study information

Scientific Title

Simultaneous Administration of Lorazepam and Levetiracetam in nonconvulsive Status Epilepticus, followed by intravenous valproate

## **Acronym**

SALLISE

## **Study objectives**

Our objectives were to assess:

1. Whether intravenous (IV) levetiracetam could be administered safely in the treatment of non-convulsive status epilepticus
2. Whether it was efficacious in terminating nonconvulsive status epilepticus quickly when administered together with IV lorazepam
3. Whether it was efficacious in preventing relapse within 12 hours after treatment

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Ethics Committee, UZ Leuven (ref: ML3691)

## **Study design**

Prospective, randomised, placebo-controlled, double-blind pilot trial.

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Nonconvulsive status epilepticus

## **Interventions**

All patients will receive the standard first-line treatment for status epilepticus during EEG recording.

Standard treatment: Intravenous (IV) lorazepam 0.05 mg/kg administered over 5 minutes, followed by valproate 30 mg/kg IV administered over 5 minutes.

For the Intervention group, levetiracetam (2,500 mg) will also be administered simultaneously with the lorazepam mentioned above.

For the Control group, placebo will be administered simultaneously with the lorazepam in the same manner as for the Intervention group.

Vital signs, including blood pressure, pulse and respiratory rate will be assessed before and after the lorazepam or lorazepam + levetiracetam administration, and after administration of valproate.

In this protocol, we have reduced the dose of lorazepam from the standard 0.1 mg/kg in view of side effects, including hypotension and hypoventilation in around 20% of cases. If status

epilepticus was not controlled, other antiepileptic drugs will be given at the discretion of the treating neurologist. There will be no repeat administration of IV levetiracetam after 12 hours.

### **Intervention Type**

Drug

### **Phase**

Not Specified

### **Drug/device/biological/vaccine name(s)**

Lorazepam, Levetiracetam, valproate

### **Primary outcome(s)**

Responder rate immediately after IV administration of lorazepam and before administration of valproate, comparing the group that received placebo versus the group that received levetiracetam.

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

1. Responder rate immediately after IV administration of valproate, comparing the group that received placebo versus the group that received levetiracetam
2. Responder rate 12 hours after IV administration of lorazepam and valproate, comparing the group that received placebo versus the group that received levetiracetam
3. Side effects 30 days after treatment
4. Glasgow Outcome Scale 30 days after treatment

### **Completion date**

31/03/2010

## **Eligibility**

### **Key inclusion criteria**

1. Adult male and female patients
2. Nonconvulsive SE (NCSE), and more specifically, complex partial SE (CPSE) and SE in coma. NCSE is defined as a change in behaviour and/or mental status from baseline associated with electroencephalogram (EEG) changes consistent with SE. We subdivide CPSE into i) CPSE in patients with epilepsy and ii) CPSE de novo. We consider subtle SE as a subgroup of SE in coma. Subtle SE is defined as SE that evolved from convulsive seizures to seizures with minor motor manifestations, such as muscle twitches, tonic eye deviation and nystagmoid eye jerks, and ictal EEG changes.

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

All

### **Key exclusion criteria**

1. Postanoxic myoclonus or myoclonic status epilepticus
2. Organic or psychogenic pseudoseizures
3. Coma with the following EEG patterns:
  - 3.1. Periodic lateralised epileptiform discharges (PLEDs)
  - 3.2. Bilateral independent periodic lateralised epileptiform discharges (BiPLEDs)
  - 3.3. Periodic epileptiform discharges (PEDs)
  - 3.4. Generalized periodic epileptiform discharges
  - 3.5. Stimulus-induced rhythmic periodic ictal-like discharges (SIRPIDs)
  - 3.6. Triphasic waves
4. Cases that are doubtful on electroclinical grounds, in whom a diagnosis of SE would only be made a posteriori after a therapeutic trial with anti-epileptic drugs
5. Current treatment with levetiracetam
6. Contraindications for administration of valproic acid (VPA), such as hepatitis, mitochondrial disease, pancreatitis, pregnancy and hepatic porphyria

Note: The following are not part of the exclusion criteria:

1. Prior treatment for seizures
2. Renal failure

### **Date of first enrolment**

01/04/2008

### **Date of final enrolment**

31/03/2010

## **Locations**

### **Countries of recruitment**

Belgium

### **Study participating centre**

**UZ Leuven**

Leuven

Belgium

3000

## **Sponsor information**

### **Organisation**

UZ Leuven (Belgium)

### **ROR**

<https://ror.org/0424bsv16>

# Funder(s)

## Funder type

Hospital/treatment centre

## Funder Name

UZ Leuven (Main funder) (Belgium)

## Funder Name

UCB Pharma will provide levetiracetam and an EEG (Belgium)

# Results and Publications

## Individual participant data (IPD) sharing plan

Not provided at time of registration

## IPD sharing plan summary

Not provided at time of registration

## Study outputs

| Output type                                   | Details                       | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|-------------------------------|--------------|------------|----------------|-----------------|
| <a href="#">Basic results</a>                 |                               | 13/03/2021   | 19/05/2022 | No             | No              |
| <a href="#">Participant information sheet</a> | Participant information sheet | 11/11/2025   | 11/11/2025 | No             | Yes             |
| <a href="#">Study website</a>                 | Study website                 | 11/11/2025   | 11/11/2025 | No             | Yes             |