ISRCTN95396292 https://doi.org/10.1186/ISRCTN95396292

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

Submission date	Recruitment status	[_] Prospectively registered
12/03/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/04/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
19/05/2022	Nervous System Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Wim van Paesschen

Contact details
UZ Leuven
Neurology
49 Herestraat
Leuven
Belgium
3000
-
Wim.vanpaesschen@uz.kuleuven.ac.be

Additional identifiers

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

Protocol serial number
N/A

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 is 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?
Basic results		13/03/2021	19/05/2022	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes