

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

Submission date 12/03/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 30/04/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 19/05/2022	Condition category 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

Study website

<http://www.neurology-kuleuven.be/?id=193>

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

2008-001098-13

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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 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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Patient information can be found at (in Dutch): <http://www.neurology-kuleuven.be/docs/NCSE%20IV%20LEV%20Informed%20consent.doc>

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 measure

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.

Secondary outcome measures

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

Overall study start date

01/04/2008

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

Age group

Adult

Sex

Both

Target number of participants

80

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)

Sponsor details

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info@uzleuven.be

Sponsor type

Hospital/treatment centre

Website

<http://www.uzleuven.be/>

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

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**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