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# Milrinone treatment versus conventional standard management for children with enterovirus 71-induced pulmonary oedema and /or neurogenic shock

**Submission date**
03/08/2010

**Registration date**
02/09/2010

**Last Edited**
29/08/2013

**Recruitment status**
No longer recruiting

**Overall study status**
Completed

**Condition category**
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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

## Contact information

**Type(s)**
Scientific

**Contact name**
Prof Ching-Chuan Liu

**Contact details**
Pediatrics Department
No. 138 Sheng-Li Road
Tainan
Taiwan
70428

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
N/A

# Study information

### Scientific Title
A randomised controlled trial examing the efficacy of Milrinone in reducing mortality in enterovirus 71-induced pulmonary oedema and/or neurogenic shock

### Study objectives
The efficacy of Milrinone administered to EV71-induced pulmonary oedema and/or neurogenic shock will reduce mortality rate in acute phase (within 1 week)

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
The ethics committee of Children's Hospital No. 1 Ho Chi Minh City (HCMC) approved on the 12th of July 2006 (ref: 4820/UBND-VX)

### Study design
Single centre randomised interventional treatment trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Hospital

### Study type(s)
Treatment

### Participant information sheet
Not available in web format, please use contact details below to request a patient information sheet

### Health condition(s) or problem(s) studied
Enterovirus 71-induced pulomnary oedema and/or neurogenic shock

### Interventions
The eligible enrolled patients were randomized to receive either
1. Group A: medical (milrinone) treatment:
Milrinone (Primacor®) was administered to the subjects who met the study criteria. The drug was administered intravenously within 2-6 hours after pulmonary oedema was diagnosed at a loading dose 50ug/kg I.V. over 15 minutes followed by a continuous infusion of 0.5ug/kg/min; dosage range of 0.35-0.55ug/kg/min; titrate dose to effect. Therapy was continued for 72 hours.
2. Group B: conventional standard management (supportive acre without milrinone treatment).

All the enrolled subjects received standard medical attention with the same critical care protocol. In addition to routine biochemistry and blood counting examination on trial entry,

enterovirus 71 infections were examined by isolation of virus or molecular test from throat /stool swabs or cerebro-spinal fluid (CSF) or serologic assay for neutralizing antibody titer.

### Intervention Type
Drug

### Phase
Phase III

### Drug/device/biological/vaccine name(s)
Milrinone (Primacor®)

### Primary outcome measure
To assess the efficacy of Milrinone as evaluated by the 1-week mortality in EV71 infected children with pulmonary oedema and/or neurogenic shock.

Each enrolled subject was followed with a standard critical care protocol until he or she was discharged from hospital or expired. Evaluation was performed when necessary for all the enrolled subjects during their hospital stays.

### Secondary outcome measures
N/A

### Overall study start date
01/06/2007

### Completion date
31/05/2010

## Eligibility

### Key inclusion criteria
1. Paediatric patients, EV71 brainstem encephalitis with pulmonary oedema and/or neurogenic shock.
2. EV71 infection was confirmed by isolation of virus or molecular test (real-time PCR) from at least one site (throat swab, stool swab, cerebrospinal fluid (CSF) or other specimens), or serologic assay (neutralizing antibody titre).
3. Stage Definitions
Stage IIIB, cardiopulmonary collapse with the occurrence of pulmonary oedema and/or neurogenic shock.

### Participant type(s)
Patient

### Age group
Child

### Sex
Both

### Target number of participants
sample size 16-29 in each group

### Key exclusion criteria
1. History of congenital heart disease
2. History of pulmonary disorder
3. Known or suspected impairment of immunologic function
4. Known hypersensitivity to any component of Milrinone
5. Prior administration of Milrinone
6. Any condition, which, in the opinion of the investigator, may interfere with the evaluation of the study objectives.

### Date of first enrolment
01/06/2007

### Date of final enrolment
31/05/2010

## Locations

### Countries of recruitment
Taiwan

Viet Nam

### Study participating centre
**Pediatrics Department**
Tainan
Taiwan
70428

## Sponsor information

### Organisation
National Health Research Institutes (NHRI) (Taiwan)

### Sponsor details
Division of Infectious Diseases
35 Keyan Road
Zhunan, Miaoli County
Taiwan
350

### Sponsor type
Research organisation

**Website**
http://english.nhri.org.tw/

**ROR**
https://ror.org/02r6fpx29

# Funder(s)

**Funder type**
Research organisation

**Funder Name**
National Health Research Institutes (NHRI) (Taiwan)

# Results and Publications

**Publication and dissemination plan**
Not provided at time of registration

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Not provided at time of registration

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 01/07/2013 | | Yes | No |