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

Submission date	<b>Recruitment status</b> No longer recruiting	Prospectively registered		
03/08/2010		[] Protocol		
Registration date	Overall study status	Statistical analysis plan		
02/09/2010	Completed	[X] Results		
Last Edited 29/08/2013	<b>Condition category</b> Infections and Infestations	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

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