

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

Submission date

03/08/2010

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

02/09/2010

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

29/08/2013

Condition category

Infections and Infestations

☐ 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

Protocol serial number

N/A

Study information

Scientific Title

A randomised controlled trial examining 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

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Enterovirus 71-induced pulmonary 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 care 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(s)

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.

Key secondary outcome(s)

N/A

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

Healthy volunteers allowed

No

Age group

Child

Sex

All

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)

ROR

<https://ror.org/02r6fpx29>

Funder(s)

Funder type

Research organisation

Funder Name

National Health Research Institutes (NHRI) (Taiwan)

Results and Publications

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes