

TCTR ID : TCTR20210427006

Overall Recruitment Status : Pending (Not yet recruiting)

OTHER ID :

Prospective registration
This protocol was registered before enrollment of the first participant.

Tracking Information

First Submitted Date : 27 April 2021
First Posted Date : 27 April 2021
Last Update Posted Date : 27 April 2021

Title

Public Title : Effect of Vitamin C supplementary in Childhood pneumonia
Acronym : No Data
Scientific Title : Effect of Vitamin C supplementary in Childhood pneumonia
Sponsor ID/ IRB ID/ EC ID : VITC1
Registration Site : Thai Clinical Trials Registry
URL : <https://www.thaiclinicaltrials.org/show/TCTR20210427006>
Secondary ID : No Secondary ID

Ethics Review

1. Board Approval : Submitted, approved
Approval Number : P-3-0149/2563
Date of Approval : 24 February 2021
Board Name : Naresuan University International Review Board
Board Affiliation : Naresuan University
Board Contact : Business Phone : 055965296 Ext. No Data
Business Email : nu-irb-board3@nu.ac.th
Business Address : 99 Moo9, Tha Pho subdistrict, Mueng, Phitsanulok 65000

Sponsor

Source(s) of Monetary or Material Supports : Naresuan University Hospital
Study Primary Sponsor : Naresuan University Hospital
Responsible Party : Name/Official Title : Naresuan University Hospital
Organization : Naresuan University Hospital
Phone : 0851888128 Ext. No Data
Email : chutimaph@nu.ac.th
Study Secondary Sponsor : No Study Secondary Sponsor

Protocol Synopsis

Protocol Synopsis : Protocol synopsis
Primary objectives: 1.Effect of vitamin C supplement in children with pneumonia
2. Optimal dose of vitamin c supplement for childhood pneumonia
Secondary objectives: 1.Plasma vitamin c level in childhood pneumonia
2. Relationship of vitamin c with severity of childhood pneumonia
Study design: Randomized double blind control trial
Study treatment: Control drug: NSS intravenous q 6hr, Treatment group 1: vitamin c 15 mg per kg per dose intravenous q 6 hr , Treatment group 2: vitamin c 30mg per kg per dose intravenous q 6 hr
Treatment duration : minimal dose is 9 and maximum is 12 dose depend in early discharge
Study endpoint
To assess
1. Clinical symptom with ReSVinet scale
2. Length of hospitalization
3. Plasma vitamin C level
4. Side effect and complication of vitamin C supplement
Sample size
Total sample size is 150 people

URL not available

Health Conditions

Health Condition(s) or Problem(s) Studied : childhood pneumonia

Keywords : child, pneumonia, hospitalization, vitamin c

Eligibility

Inclusion Criteria : 1.children between 2 month of age and 15 years old
2. Diagnosis of pneumonia which need for hospitalization

Gender : Both

Age Limit : Minimum : 2 Months Maximum : 15 Years

Exclusion Criteria : 1. Malnutrition according to WHO criteria (W/A below - 2SD)
2. Recieved vitamin c supplement within 1 week prior to admission
3. Any significant underlying disease such as chronic lung disease , congenital and acquired heart disease, congenital malformatin of respiratory tract, asthma, hematologic and solid malignancy, chronic liver disease, immunocompromised host or received immunosuppressive drug
4. Severe pneumonia which need intensive crase such as endotracheak tube intubation
5. Pneumonia with complication
6. Hemodynsmic unstablitiy
7. Renal insufficiency
8. History of vitamin C allergy
9. G6PD deficiency
10. Administration of erythromycins, streptomycin, doxycycline and warfarin

Accept Healthy Volunteers : No

Status

Overall Recruitment Status : Pending (Not yet recruiting)

Key Trial Dates	Study Start Date (First enrollment) : 01 June 2021	Indicate Type : Anticipated
	Completion Date (Last subject, Last visit) : 31 May 2022	Indicate Type : Anticipated
	Study Completion Date : 31 December 2022	Indicate Type : Anticipated

Design

Study Type : Interventional

Primary Purpose : Treatment

Study Phase : Phase 2/Phase 3

Intervention Model : Others

Number of Arms : 3

Masking : Masked Masked Role : Subject,

Allocation : Randomized

Control : Placebo

Study Endpoint Classification : Efficacy Study

Sample size

Planned sample size : 150

Intervantion Arm 1

Intervention name : Control group

Intervention Type : Experimental

Intervention Classification : Drug

Intervention Description : NSS administration

Intervantion Arm 2

Intervention name : vitamin c gr 1

Intervention Type : Experimental

Intervention Classification : Drug

Intervention Description : vitamin c 15 mg per kg per dose iv q 6 hr

Intervantion Arm 3

Intervention name : vitamin c gr 2

Intervention Type : Experimental
Intervention Classification : Drug
Intervention Description : vitamin c 30 mg per kg per dose iv q 6 hr

Outcome

Primary Outcome

1. Outcome Name : effect
Metric / Method of measurement : duration of hospitalization
Time point : 30 days

Secondary Outcome

1. Outcome Name : clinical status
Metric / Method of measurement : ReSVinet scale
Time point : 3 days or until discharge

Location

Section A : Central Contact

Central Contact	First Name : Chutima	Middle Name :	Last Name : Phuaksaman
	Degree : MD	Phone : 0851888128 Ext. : No Data	Email : chutimaph@nu.ac.th
Central Contact Backup	First Name : Klaita	Middle Name :	Lastname : Srisingh
	Degree : MD	Phone : 0897036724 Ext. : No Data	Email : klaitas@nu.ac.th

Section B Facility Information and Contact

1. Site Name : Naresuan University Hospital
City : Phitsanulok State/Province : Phitsanulok Postal Code : 65000
Country : Thailand Recruitment Status : Pending (Not yet recruiting)

Facility Contact	First Name : Chutima	Middle Name :	Last Name : Phuaksaman
	Degree : MD	Phone : 0851888128 Ext. : No Data	Email : chutimaph@nu.ac.th
Facility Contact Backup	First Name : Klaita	Middle Name :	Last Name : Srisingh
	Degree : MD	Phone : 0897036724 Ext. : No Data	Email : klaitas@nu.ac.th
Investigator Name	First Name : Chutima	Middle Name :	Last Name : Phuaksaman
	Degree : MD	Role : Principal Investigator	

Section C : Contact for Public Queries (Responsible Person)

First Name : Chutima	Middle Name :	Last Name : Phuaksaman
Degree : MD	Phone : 0851888128 Ext. : No Data	Email : chutimaph@nu.ac.th
Postal Address : 99 Moo 9, Tha Pho subdistrict, Mueng		
State/Province : Phitsanulok	Postal Code : 65000	
Country : Thailand	Official Role : Study Principal Investigator	
Organization Affiliation : Naresuan University Hospital		

Section D : Contact for Scientific Queries (Responsible Person)

First Name : Chutima	Middle Name :	Last Name : Phuaksaman
Degree : MD	Phone : 0851888128 Ext. : No Data	Email : chutimaph@nu.ac.th
Postal Address : 99 Moo 9 , Tha Pho subdistrict, Mueng		
State/Province : Phitsanulok	Postal Code : 65000	
Country : Thailand	Official Role : Study Principal Investigator	
Organization Affiliation : Naresuan University Hospital		

Deidentified Individual Participant-level Data Sharing

Plan to share IPD : No
Reason : due to security of patient information

Publication from this study

MEDLINE Identifier : No Data
URL link to full text publication : No Data

