

**TCTR ID : TCTR20220507003**

Overall Recruitment Status : Recruiting

**OTHER ID :**

Retrospective registration  
This protocol was registered after enrollment of the first participant.

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**Tracking Information**

First Submitted Date : 05 May 2022  
First Posted Date : 07 May 2022  
Last Update Posted Date : 05 May 2022

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**Title**

Public Title : The Effect of peptide-based formula compared with isocaloric, isonitrogenous formula by early enteral feeding in critically-ill patients  
Acronym : No Data  
Scientific Title : The Effect of peptide-based formula compared with isocaloric, isonitrogenous formula by early enteral feeding in critically-ill patients  
Sponsor ID/ IRB ID/ EC ID : NPD-TOP-2018-01  
Registration Site : Thai Clinical Trials Registry  
URL : <https://www.thaiclinicaltrials.org/show/TCTR20220507003>  
Secondary ID : No Secondary ID

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**Ethics Review**

- Board Approval : Submitted, approved  
Approval Number : R-31061530  
Date of Approval : 29 October 2018  
Board Name : Committee on Human Rights Related to Research Involving Human Subjects  
Board Affiliation : Faculty of Medicine, Ramathibodi Hospital  
Board Contact : Business Phone : 022011544 Ext. No Data  
Business Email : raec.mahidol@gmail.com  
Business Address : 270 Thanon Rama VI, Thung Phaya Thai, Ratchathewi, Bangkok 10400
- Board Approval : Submitted, approved  
Approval Number : 21/62/S/h1  
Date of Approval : 20 March 2019  
Board Name : Chonburi Hospital Institutional Review Board  
Board Affiliation : MOPH  
Board Contact : Business Phone : 038932036 Ext. No Data  
Business Email : cbhresearch@gmail.com  
Business Address : 69 Moo 2 Sukhumvit Road Ban suan sub-district, Mueang District, Chonburi Province 20000
- Board Approval : Submitted, approved  
Approval Number : 59/2561  
Date of Approval : 02 November 2018  
Board Name : Ethic committee, Medical Staff Organization of Surin Hospital  
Board Affiliation : MOPH  
Board Contact : Business Phone : 044511757 Ext. No Data  
Business Email : research.hospitalsurin@gmail.com  
Business Address : 68 Lak Mueang Road, Nai Mueang Subdistrict, Mueang Surin District, Surin 32000

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**Sponsor**

Source(s) of Monetary or Material Supports : Thai Otsuka Pharmaceutical Co., Ltd  
Study Primary Sponsor : Thai Otsuka Pharmaceutical Co., Ltd  
Responsible Party : Name/Official Title : Thipvadee Yamchuenpong  
Organization : Thai Otsuka Pharmaceutical Co., Ltd

Phone : 0632378178 Ext. No Data  
Email : thipvadee@thai-otsuka.co.th

Study Secondary Sponsor : No Study Secondary Sponsor

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### Protocol Synopsis

Protocol Synopsis : This study is about to compare efficacy and safety between peptide-based formulas and standard polymeric formula in surgery critically-ill patients who is on tube-feeding. The subjects will be assigned the randomized formulas and prescribed early enteral feeding for 14 days (adjust follow energy requirement in each patient). They will be assessed about daily average gastric residual volume, nutritional status, electrolyte , inflammatory parameter, wound healing parameter and side effects from enteral feeding throughout the study.

### URL not available

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### Health Conditions

Health Condition(s) or Problem(s) Studied : Critically-ill patients who admitted on Surgical ICU ward and can start tube feeding after 48 hr post-operation.

Keywords : Peptide-based formula tube feeding critically-ill Surgical ICU

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### Eligibility

Inclusion Criteria : 1.Willing to participate clinical study with signing consent form  
2.Age 15 year or above  
3.Admit on Surgical ICU ward  
4.Tend to be prescribed tube feeding in ICU at least 5 days and up to 14 days  
5.Risk of malnutrition on mild to moderate by BNT assessment  
6.BMI 18-40 kg/m<sup>2</sup>  
7.Can be assigned tube feeding within 48 hr after operation  
8.Haemodynamic stable. In case of taking norepinephrine, would take not more than 15 microgram/min or 0.3 microgram/kg/min

Gender : Both

Age Limit : Minimum : 15 Years Maximum : 90 Years

Exclusion Criteria : 1. Experiences aspiration pneumonia  
2. Experiences thyroid disease  
3. Experiences severe hepatic impairment  
4. Diagnosed to ascites  
5. Diagnosed to CKD or renal replacement therapy  
6. Diagnosed to abdominal hypertension or fluid overload  
7. Takes fentanyl more than 2 microgram per kg per hr or morphine more than 0.05 milligram per kg per hr  
8. Has parenteral nutrition administration  
9. Experiences food allergy such as Whey Protein, Casein ,  
10 Diagnosed to incurable disease that could not participate the study such as uncontrolled cancer,  
11 Experiences chemotherapy or radiotherapy within 6 months ago. (including immunosuppressor taking such as prednisolone 7 days continuously within 4 months before enrolment ,  
12 Experiences immune disorder such as HIV-positive  
13. Diagnosed to burn at severity level 2 or 3 with wound 50% of total body surface area  
14. Taking tube feeding less than 70% of total requirement

Accept Healthy Volunteers : No

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### Status

Overall Recruitment Status : Recruiting

Key Trial Dates	Study Start Date (First enrollment) : 22 June 2019	Indicate Type : Actual
	Completion Date (Last subject, Last visit) : 30 June 2022	Indicate Type : Anticipated
	Study Completion Date : 30 June 2022	Indicate Type : Anticipated

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### Design

Study Type : Interventional  
Primary Purpose : Treatment  
Study Phase : Phase 3  
Intervention Model : Parallel  
Number of Arms : 2

Masking : Masked    Masked Role : Allocation concealment, Subject, Caregiver, Investigator,  
Allocation : Randomized  
Control : Placebo  
Study Endpoint Classification : Safety/Efficacy Study  
Sample size  
Planned sample size : 54

Intervention Arm 1  
Intervention name : Peptide-based formula  
Intervention Type : Active Comparator  
Intervention Classification : Other  
Intervention Description : Peptide-based formula will be given via feeding tube for 14 days (4 feeds per day)  
. Dose will be adjusted follow individual calories requirement

Intervention Arm 2  
Intervention name : Standard polymeric formula  
Intervention Type : Placebo Comparator  
Intervention Classification : Other  
Intervention Description : Standard polymeric formula will be given via feeding tube for 14 days (4 feeds per day)  
. Dose will be adjusted follow individual calories requirement

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## Outcome

### Primary Outcome

1. Outcome Name : Daily average gastric residual volume  
Metric / Method of measurement : Gastric Residual Volume measurement  
Time point : every time before feeding IP
2. Outcome Name : Fibronectin change  
Metric / Method of measurement : Fibronectin level  
Time point : Day1,3,5,11,14

### Secondary Outcome

1. Outcome Name : Nutrition status  
Metric / Method of measurement : retinol binding protein, prealbumin, albumin  
Time point : Day1,3,5,7,9,11,14
2. Outcome Name : total lymphocyte count  
Metric / Method of measurement : CBC  
Time point : Day 1,3,5,7,9,11,14
3. Outcome Name : nitrogen balance  
Metric / Method of measurement : UUN  
Time point : Day 1,3,5,7,9,11,14
4. Outcome Name : ICU length of stay  
Metric / Method of measurement : assessment  
Time point : Everyday during the study
5. Outcome Name : ICU mortality  
Metric / Method of measurement : assessment  
Time point : Everyday during the study
6. Outcome Name : duration of hospitalization  
Metric / Method of measurement : assessment  
Time point : Everyday during the study
7. Outcome Name : GI side effect  
Metric / Method of measurement : assessment  
Time point : Everyday during the study
8. Outcome Name : Rate of infection  
Metric / Method of measurement : assessment  
Time point : Everyday during the study

**Location**

**Section A : Central Contact**

Central Contact	First Name : Thipvadee	Middle Name :	Last Name : Yamchuenpong
	Degree :	Phone : 0632378178 Ext. : No Data	Email : thipvadee@thai-otsuka.co.th
Central Contact Backup	First Name : Thanaporn	Middle Name :	Lastname : Manjong
	Degree :	Phone : 0655173735 Ext. : No Data	Email : thanaporn.man@thai-otsuka.co.th

**Section B Facility Information and Contact**

1. Site Name : Faculty of Medicine, Ramathibodi Hospital  
 City : Ratchathewi State/Province : Bangkok Postal Code : 10400  
 Country : Thailand Recruitment Status : Recruiting

<b>Facility Contact</b>	First Name : Thipvadee	Middle Name :	Last Name : Yamchuenpong
	Degree :	Phone : 0632378178 Ext. : No Data	Email : thipvadee@thai-otsuka.co.th

<b>Facility Contact Backup</b>	First Name : Thanaporn	Middle Name :	Last Name : Manjong
	Degree :	Phone : 0655173735 Ext. : No Data	Email : thanaporn.man@thai-otsuka.co.th

<b>Investigator Name</b>	First Name : Assoc.Prof. Preeda	Middle Name :	Last Name : Sumritpradit
	Degree :	Role : Principal Investigator	

2. Site Name : Chonburi Hospital  
 City : Mueang State/Province : Chonburi Postal Code : 20000  
 Country : Thailand Recruitment Status : Recruiting

<b>Facility Contact</b>	First Name : Thipvadee	Middle Name :	Last Name : Yamchuepong
	Degree :	Phone : 0632378178 Ext. : No Data	Email : thipvadee@thai-otsuka.co.th

<b>Facility Contact Backup</b>	First Name : Thanaporn	Middle Name :	Last Name : Manjong
	Degree :	Phone : 0655173735 Ext. : No Data	Email : thanaporn.man@thai-otsuka.co.th

<b>Investigator Name</b>	First Name : Dr.Pinit	Middle Name :	Last Name : Noorit
	Degree :	Role : Site Sub-Investigator	

3. Site Name : Surin Hospital  
 City : Mueang State/Province : Surin Postal Code : 32000  
 Country : Thailand Recruitment Status : Recruiting

<b>Facility Contact</b>	First Name : Thipvadee	Middle Name :	Last Name : Yamchuenpong
	Degree :	Phone : 0632378178 Ext. : No Data	Email : thipvadee@thai-otsuka.co.th

<b>Facility Contact Backup</b>	First Name : Thanaporn	Middle Name :	Last Name : Manjong
	Degree :	Phone : 0655173735 Ext. : No Data	Email : thanaporn.man@thai-otsuka.co.th

<b>Investigator Name</b>	First Name : Winai	Middle Name :	Last Name : Ungpinitpong
	Degree :	Role : Site Sub-Investigator	

**Section C : Contact for Public Queries (Responsible Person)**

First Name : Thipvadee	Middle Name :	Last Name : Yamchuenpong
Degree : No Data	Phone : 0632378178 Ext. : No Data	Email : thipvadee@thai-otsuka.co.th
Postal Address : THAI OTSUKA PHARMACEUTICAL CO., LTD. Address, 15th Floor Unit 1501-1502, United Center Bldg 323 Silom Road, Silom, Bangrak Bangkok 10500, Thailand		
State/Province : Bangkok	Postal Code : 10500	
Country : Thailand	Official Role : Study Chair	
Organization Affiliation : THAI OTSUKA PHARMACEUTICAL CO., LTD		

**Section D : Contact for Scientific Queries (Responsible Person)**

First Name : Thipvadee	Middle Name :	Last Name : Yamchuenpong
Degree : No Data	Phone : 0632378178 Ext. : No Data	Email : thipvadee@thai-otsuka.co.th
Postal Address : THAI OTSUKA PHARMACEUTICAL CO., LTD. Address, 15th Floor Unit 1501-1502, United Center Bldg 323 Silom Road, Silom, Bangrak Bangkok 10500, Thailand		
State/Province : Bangkok	Postal Code : 10500	

Country : Thailand

Official Role : Study Chair

Organization Affiliation : THAI OTSUKA PHARMACEUTICAL CO., LTD.

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**Deidentified Individual Participant-level Data Sharing**

Plan to share IPD : No

Reason : The subject information is confidential.

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**Publication from this study**

MEDLINE Identifier : No Data

URL link to full text publication : No Data

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