ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: December 31, 2018

ClinicalTrials.gov ID: NCT03791866

Study Identification

Unique Protocol ID:	YKK17102
Brief Title:	The Th9/IL-9 and Early Enteral Nutrition in Sepsis
Official Title:	The Roles of Th9/IL-9 in the Mechanisms of Early Enteral Nutrition Maintaining Intestinal Mucosal Barrier in Sepsis
Secondary IDs:	

Study Status

Record Verification:	December 2018
Overall Status:	Recruiting
Study Start:	October 1, 2018 [Actual]
Primary Completion:	December 31, 2019 [Anticipated]
Study Completion:	June 30, 2020 [Anticipated]

Sponsor/Collaborators

Sponsor:	Nanjing First Hospital, Nanjing Medical University
Responsible Party:	Principal Investigator Investigator: XiangWang [xiangw] Official Title: Director Affiliation: Nanjing First Hospital, Nanjing Medical University
Collaborators:	

Oversight

U.S. FDA-regulated Drug:	No
U.S. FDA-regulated Device:	No
U.S. FDA IND/IDE:	No
Human Subjects Review:	Board Status: Approved Approval Number: KY20180713-01 Board Name: The institutional review board of Nanjing First Hospital Board Affiliation: Nanjing First Hospital Phone: +86-13913893984 Email: 565219791@qq.com Address: Nanjing First Hospital, 68 Changle Road, Nanjing, Jiangsu Province, China

Data Monitoring:

Study Description

Brief Summary: The investigators aim to evaluate the roles of Th9/IL-9 in the mechanisms of early enteral nutrition (EEN) maintaining intestinal mucosal barrier in sepsis. The results of this study would lay the foundation for revealing the mechanisms of EEN improving immune imbalance of sepsis and provide a new idea to the early treatment of sepsis. In addition, the investigators also aim to evaluate the effects of different proportions of target total enteral nutrition on the prognosis of sepsis.

Detailed Description:

Conditions

Conditions: Sepsis
Intestinal Mucosal Barrier
Th9 Cells
Enteral Nutrition

Keywords:

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: N/A

Interventional Study Model: Parallel Assignment

Number of Arms: 3

Masking: Double (Participant, Care Provider)

Allocation: Randomized

Enrollment: 60 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions
Experimental: 30% target total enteral nutrition	Nutrition Enteral nutrition
Experimental: 60% target total enteral nutrition	Nutrition Enteral nutrition
Active Comparator: 100% target total enteral nutrition	Nutrition Enteral nutrition

Outcome Measures

Primary Outcome Measure:

1. 28-d mortality
   [Time Frame: 28 days]

Secondary Outcome Measure:

2. Serum Th9 lymphocyte percentages
   Serum Th9 lymphocyte percentages

   [Time Frame: 7 days]
3. Concentration of serum IL-9
   Concentration of serum IL-9

   [Time Frame: 7 days]
4. Concentration of serum iFABP
   Concentration of serum iFABP

   [Time Frame: 7 days]
5. Concentration of serum DAO
   Concentration of serum DAO

   [Time Frame: 7 days]

Eligibility

Minimum Age:	18 Years
Maximum Age:	70 Years
Sex:	All
Gender Based:	
Accepts Healthy Volunteers:	No
Criteria:	Inclusion Criteria: 1. Clinical diagnosis of sepsis 2. Within 3 days of sepsis onset before ICU admission 3. No artificial nutrition (enteral or parenteral nutrition) were provided before ICU admission Exclusion Criteria: 1. Ileus 2. Digestive tract hemorrhage 3. Inflammatory bowel disease 4. Abdominal hypertension (IAP >25mmHg) 5. Cancer or chronic organ dysfunction (e.g., hepatic or renal dysfunction) 6. Malnutrition or immunodeficiency 7. Long-term use of hormones

Contacts/Locations

Central Contact Person:	Jie Zhou Telephone: +8613913893984 Email: 565219791@qq.com
Central Contact Backup:	
Study Officials:	Jia-Kui Sun Study Principal Investigator The First Affiliated Hospital with Nanjing Medical University

Locations:	China, Jiangsu Nanjing First Hospital [Recruiting]

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IPDSharing

Plan to Share IPD:

References

Citations:

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Available IPD/Information: