**ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt**
Release Date: March 2, 2019

**ClinicalTrials.gov ID: NCT03385850**

## Study Identification

| | |
|---|---|
| Unique Protocol ID: | NanjingFirst |
| Brief Title: | The Th17/Treg Cells and IL-23/IL-17 Axis and Early Enteral Nutrition in Sepsis |
| Official Title: | The Roles of Th17/Treg Cells and IL-23/IL-17 Axis in the Mechanisms of Early Enteral Nutrition Improving Immune Function of Sepsis |
| Secondary IDs: | |

## Study Status

| | |
|---|---|
| Record Verification: | March 2019 |
| Overall Status: | Completed |
| Study Start: | October 1, 2017 [Actual] |
| Primary Completion: | June 30, 2018 [Actual] |
| Study Completion: | December 31, 2018 [Actual] |

## Sponsor/Collaborators

| | |
|---|---|
| Sponsor: | Nanjing First Hospital, Nanjing Medical University |
| Responsible Party: | Principal Investigator<br>Investigator: XiangWang [xiangw]<br>Official Title: Director<br>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<br>Approval Number: KY20170921-02<br>Board Name: The institutional review board of Nanjing First Hospital<br>Board Affiliation: Nanjing First Hospital<br>Phone: +86-13913893984<br>Email: 565219791@qq.com<br>Address:<br><br>Nanjing First Hospital, 68 Changle Road, Nanjing, Jiangsu Province, China |

Data Monitoring:

## Study Description

Brief Summary: The investigators aim to evaluate the roles of Th17/Treg cells and IL-23/IL-17 axis in the mechanisms of early enteral nutrition (EEN) correcting immune imbalance of sepsis by means of improving the intestinal flora disturbance. 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

Detailed Description:

## Conditions

Conditions: Sepsis
Immune System Disorder
Enteral Feeding

Keywords:

## Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: N/A

Interventional Study Model: Parallel Assignment

Number of Arms: 2

Masking: Single (Participant)

Allocation: Randomized

Enrollment: 53 [Actual]

## Arms and Interventions

| Arms | Assigned Interventions |
|---|---|
| Experimental: early enteral nutrition | enteral nutrition<br>early enteral nutrition group or delayed enteral nutrition group |
| Active Comparator: delayed enteral nutrition | enteral nutrition<br>early enteral nutrition group or delayed enteral nutrition group |

## Outcome Measures

Primary Outcome Measure:

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

Secondary Outcome Measure:

2. immune parameters
   serum Th17 and Treg lymphocyte percentages

[Time Frame: 7 days]

3. immune parameters
   IL-23, IL-17, IL-6, IL-10 levels

   [Time Frame: 7 days]

## Eligibility

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

## Contacts/Locations

| | |
|---|---|
| Central Contact Person: | Jie Zhou<br>Telephone: +8613913893984<br>Email: 565219791@qq.com |
| Central Contact Backup: | |
| Study Officials: | Xiang Wang<br>Study Principal Investigator<br>The First Affiliated Hospital with Nanjing Medical University |
| Locations: | **China, Jiangsu**<br>Nanjing First Hospital<br>Nanjing, Jiangsu, China, 210000<br>Contact: Jie Zhou |

## IPDSharing

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|---|---|
| Plan to Share IPD: | Undecided<br>There is a plan to make individual participant data (IPD) available to other researchers. |

## References

Citations:

Links:

Available IPD/Information: