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审核状态: 通过审核

Project audit state: Successful

注册号: ChiCTR2200066641

Registration number:

最近更新时间: 2022/12/12 17:33:21

Date of Last Refreshed on:

注册号状态: 补注册

Registration Status: Retrospective registration

填写语言: 中文和英文

Language: Chinese And English

注册题目: 间接热量指导脓毒症患者营养支持对肠道菌群多样性的影响

Public title: Investigation of the effect of indirect calorimetry on the diversity of gut flora in patients with sepsis under nutritional support.

注册题目简写:

Public title acronym:

研究课题的正式科学名称: 间接热量指导脓毒症患者营养支持对肠道菌群多样性的影响

Scientific title: Investigation of the effect of indirect calorimetry on the diversity of gut flora in patients with sepsis under nutritional support.

研究课题的正式科学名称简写:

Scientific title acronym:

研究课题代号(代码):

Study subject ID:

在其它机构的注册号:

Secondary ID:

申请注册联系人: 杨小娟

Applicant: XiaoJuan Yang

申请注册联系人电话: 13639593480

Applicant telephone: 13639593480

申请注册联系人传真:

Applicant Fax:

申请注册联系人电子邮件: 13639593480@163.com

Applicant E-mail: 13639593480@163.com

申请单位网址(自愿提供):

Applicant website(voluntary supply):

申请注册联系人通讯地址: 宁夏银川宁夏医科大学总医院重症医学科

Applicant address: Department of Critical Care Medicine, General Hospital of Ningxia Medical University, Yinchuan ,Ningxia, China

申请注册联系人邮政编码: 750004

Applicant postcode: 750004

申请人所在单位: 宁夏医科大学总医院

Applicant's institution: General Hospital of Ningxia Medical University

研究负责人: 杨小娟

Study leader: XiaoJuan Yang

研究负责人电话: 13639593480

Study leader's telephone: 13639593480

研究负责人传真:

Study leader's fax:

研究负责人电子邮件: 13639593480@163.com

Study leader's E-mail: 13639593480@163.com

研究负责人网址(自愿提供):

Study leader's website(voluntary supply):

研究负责人通讯地址: 宁夏银川宁夏医科大学总医院重症医学科

Study leader's address: Department of Critical Care Medicine, General Hospital of Ningxia Medical University, Yinchuan ,Ningxia, China

研究负责人邮政编码: 750004

Study leader's postcode: 750004

是否获伦理委员会批准: 是

Approved by ethic committee: Yes

伦理委员会批准文号: 2017-266

Approved No. of ethic committee: 2017-266

伦理委员会批准日期:

Date of approved by ethic committee:

批准本研究的伦理委员会名称: 宁夏医科大学总医院医学科研伦理审查委员会

Name of the ethic committee: Medical Research Ethics Review Committee of General Hospital of Ningxia Medical University

伦理委员会批准日期: 2017-11-01

Date of approved by ethic committee: 2017-11-01

国家FDA批准文号: 中国

Approved No. of SFDA:

国家FDA批准日期:

Date of approved by SFDA:

国家FDA批准附件:

Approved file of SFDA:

研究实施负责 (组长) 单位: 宁夏医科大学总医院

Primary sponsor: General Hospital of Ningxia Medical University

研究实施负责 (组长) 单位地址: 中国宁夏银川宁夏医科大学总医院

Primary sponsor's address: General Hospital of Ningxia Medical University, Yinchuan ,Ningxia, China

国家: 中国

省(直辖市): 宁夏

市(区县): 银川

Country: China

Province: Ningxia

City: Yinchuan

Secondary sponsor:

单位(医院): 宁夏医科大学总医院

具体地址: 中国宁夏银川宁夏医科大学总医院

Institution hospital: General Hospital of Ningxia Medical University

Address: General Hospital of Ningxia Medical University, Yinchuan ,Ningxia, China

经费或物资来源: 宁夏自然科学基金项目

Source(s) of funding: Ningxia Natural Science Foundation Project

研究疾病: 脓毒症

Target disease: Sepsis

研究疾病代码:

Target disease code:

研究类型: 干预性研究

Study type: Interventional study

研究所处阶段: 其它

Study phase: N/A

研究目的: 从肠道微生物角度选择脓毒症患者早期营养方式。

Objectives of Study: To select a modality of early nutrition support for sepsis patients from the perspective of intestinal microecology.

研究设计: 病例对照研究

Study design: Case-Control study

纳入标准: 纳入标准: ①年龄18-75周岁; ②脓毒症患者符合2016年美国重症医学学会颁布的最新定义"Sepsis-3.0"; ③机械通气患者; ④具备营养支持的指征 (血流动力学稳定 (无/小剂量血管活性药物维持生命体征且乳酸≤2mmol/L) , 且NUTRIC评分 (危重症患者营养风险评估工具) ≥6分) 。

Inclusion criteria: The inclusion criteria are as follow: (1) aged 18-75 years; (2) have met the latest definition of sepsis of the American Society of Critical Care Medicine "Sepsis-3.0" from 2016[1]; (3) mechanically ventilated patients; and (4) indicated for nutritional support (hemodynamic stability [no dose or small dose of vasoactive drugs to maintain vital signs and lactate ≤ 2 mmol/L] and NUTRIC score [Nutritional Risk Rating Instrument for Critically Ill Patients] ≥ 6).

排除标准: 排除标准: 1. 存在胸腔、腹腔、气道损伤, 呼吸不稳定, 呼吸机参数测量期间需调整或呼吸频率过快≥35次/分或氧浓度大于60%或呼气末正压≥10cmH2O等导致呼吸机管路脱落不准调查; 2. 胃肠道、腹腔开放性损伤者; 3. 未获得家属知情同意者。

Exclusion criteria: The exclusion criteria are as follow: (1) those with chest wall, thoracic, or airway injuries, respiratory instability, ventilator parameters requiring adjustment during measurement, or rapid respiratory rate ≥ 35 breaths/min, or oxygen concentration > 60%, or positive end-expiratory pressure ≥ 10 cmH2O; (2) those with open injuries to the gastrointestinal tract or abdominal cavity; and (3) those whose family members did not provide informed consent. Informed consent was obtained from patients or immediate family members.

研究实施时间: 从From2017-12-01至To 2021-12-01

Study execute time:

组别: 全肠内营养组

Group: TEN

干预措施: 给予全肠内营养方式

Intervention: Total enteral nutrition was given

组别: 全肠外营养组

Group: TPN

干预措施: 给予全静脉营养支持

Intervention: Total intravenous nutritional support was given

组别: 补充性肠外营养组

Group: SPN

干预措施: 通过肠内营养支持+肠外营养支持方式予以营养支持

Intervention: Nutritional support was given by enteral nutrition support + parenteral nutrition support

国家: 中国

省(直辖市): 宁夏

市(区县): 银川

Country: China

Province: Ningxia

City: Yinchuan

单位(医院): 宁夏医科大学总医院

单位级别: 三级甲等医院

Institution hospital: General Hospital of Ningxia Medical University

Level of the institution: Tertiary hospital

指标中文名: 粪便16s-rRNA测序

Outcome: Fecal 16s-rRNA sequencing

测量时间点:

Measure time point of outcome:

指标中文名: 粪便短链脂肪酸

Outcome: Fecal short-chain fatty acids

测量时间点:

Measure time point of outcome:

指标中文名: 血常规及免疫指标

Outcome: Blood nutrition and immune indicators

测量时间点:

Measure time point of outcome:

指标中文名: 患者一般资料

Outcome: General information

测量时间点:

Measure time point of outcome:

指标类型: 主要指标

Type: Primary indicator

测量方法:

Measure method:

指标类型: 主要指标

Type: Primary indicator

测量方法:

Measure method:

指标类型: 主要指标

Type: Primary indicator

测量方法:

Measure method:

指标类型: 附加指标

Type: Additional indicator

测量方法:

Measure method:

标本中文名: 血液

Sample Name: Blood

人体标本去向: 使用后销毁

Fate of sample: Destruction after use

标本中文名: 粪便

Sample Name: feces

人体标本去向: 使用后销毁

Fate of sample: Destruction after use

征集研究对象情况: 结束

Recruiting status: Completed

年龄范围: 最小 Min age 43 岁 years

Participant age: 最大 Max age 75 岁 years

性别: 男女均可

Gender: Both

随机方法 (请说明由何人用什么方法产生随机序列): 随机数字表法进行分组

Randomization Procedure (please state who generates the random number sequence and by what method): The patients were divided into two groups by random number table method

UTN(全球唯一识别码):

盲法:

Blinding:

试验完成后的统计结果:

Calculated Results after the Study Completed:

研究负责(组长)单位:

Organizer institution (leader institution):

资料收集汇总单位: 6M

Data collection Institution:

资料管理单位: 原始数据已经上传至NCBI的SRA数据库, SRA编号已生成: PRJNA861102, 释放日期为2026-07-22, 链接 https://www.ncbi.nlm.nih.gov/sra/

Data management Institution: The raw data have been uploaded to the SRA database at NCBI, and the SRA number has been generated: PRJNA861102 with a release date of 2026-07-22, https://www.ncbi.nlm.nih.gov/sra/

资料分析单位: 病历记录表

Data analysis Institution: Case Record Form, CRF