

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Comparison the efficiency of nutrition with entera meal standard formula and Ensure and standard gavage of hospital in traumatic patients at ICU in Vali-Asr hospital, Arak.

#### Protocol summary

##### Study aim

Comparison the efficiency, complications and price of nutrition with entera meal standard formula and Ensure and standard gavage of hospital in traumatic patients at ICU in Vali-Asr hospital, Arak and

##### Design

A randomized, double blinded clinical trial with two intervention and one control group, three parallel group and outcome assessment

##### Settings and conduct

This trial will be performed at ICU in Arak Vali-asr hospital. 66 traumatic patients will be divided in three groups and each group has one of three formulas(Ensure\_ entera meal\_ hospital gavage). trial is double blinded and researcher and data analyser don't know the formula of each patient

##### Participants/Inclusion and exclusion criteria

.Inclusion criteria: Age 18 to 50 Need to Nutrition with NG tube or Gastrostomy or Jejunostomy Multiple trauma  
.Exclusion criteria: Death Gavage intolerance for more than 24 hours Patient re-NPO for more than 24 hours Reaction to Folate History of DM, hyper or hypothyroidism and metabolic disease Sensitivity to milk protein Gastro-intestinal fistula Burning Renal failure Hepatic failure

##### Intervention groups

.First intervention group: Entera meal standard formula \_ Dose and number of times is due to nutritional need of each patient. Duration of use is 14 days for each patient .  
Second Intervention group: Ensure formula \_ Dose and number of times is due to nutritional need of each patient. Duration of use is 14 days for each patient .  
Control group: Standard gavage of hospital \_ Dose and number of times is due to nutritional need of each patient. Duration of use is 14 days for each patient

##### Main outcome variables

.Serum total protein level . Mid arm circumflex . Serum

electrolytes: (Na, K, Ca, Mg) . NUTRIC score

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180112038319N1**

Registration date: **2018-10-27, 1397/08/05**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-10-27, 1397/08/05**

Update count: **0**

##### Registration date

2018-10-27, 1397/08/05

##### Registrant information

##### Name

Shima Shahri

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 86 3221 8317

##### Email address

sh.shahri@arakmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-10-22, 1397/07/30

##### Expected recruitment end date

2019-12-20, 1398/09/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Comparison the efficiency of nutrition with entera meal standard formula and Ensure and standard gavage of hospital in traumatic patients at ICU in Vali-Asr hospital, Arak.

**Public title**

Comparison the efficiency of nutrition with entera meal and Ensure and standard gavage of hospital in traumatic patients

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age 18 to 50 Need to Nutrition with NG tube or Gastrostomy or Jejunostomy Multiple trauma

**Exclusion criteria:**

Death Gavage intolerance for more than 24 hours Patient re-NPO for more than 24 hours Reaction to Folate History of DM, hyper or hypothyroidism and metabolic disease Sensitivity to milk protein Gastro-intestinal fistula Burning Renal failure Hepatic failure

**Age**

From **18 years** old to **50 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Investigator
- Data analyser

**Sample size**

Target sample size: **66**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization technique: Simple randomization with randomization table. Patients with similar situation will be chosen. Each patient has a number. The numbers are in randomization table and 66 numbers will be chosen randomly. All the patients have equal chances. Unit of Randomization is person. Researcher and data analyser know the number of patients but they don't know the formula of each patient.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

This clinical trial will be performed in double blind way That means researcher,data analyser,nurses, hospital personnel and the patient don't know the formula. The formula will be prepared and coded in clean room and will be given to the researcher who gives them to the patients. The preparator knows the formula and others don't know. Data Monitoring Committee possess all patient's data

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Arak University of Medical Sciences

**Street address**

Arak University of Medical Sciences,basij Sq

**City**

Arak

**Province**

Markazi

**Postal code**

1884

**Approval date**

2017-12-02, 1396/09/11

**Ethics committee reference number**

IR.ARAKMU.REC.1396.201

**Health conditions studied****1****Description of health condition studied**

traumatic patients

**ICD-10 code**

T79.9

**ICD-10 code description**

Unspecified early complication of trauma

**Primary outcomes****1****Description**

Serum total protein level: Serum albumin and globulin measurement

**Timepoint**

Serum total protein measurement at the beginning of trial(first day) and 8 and 14 days after Formula beginning.

**Method of measurement**

Blood test

**2****Description**

Mid arm circumflex

**Timepoint**

Mid arm circumflex measurement at the beginning of trial(first day) and 8 and 14 days after Formula beginning.

**Method of measurement**

non-stretchable tape measure

### 3

#### **Description**

Serum electrolytes: (Na, K, Ca, Mg)

#### **Timepoint**

Serum electrolytes measurement at the beginning of trial(first day) and 8 and 14 days after Formula beginning.

#### **Method of measurement**

Blood serum test

### 4

#### **Description**

NUTRIC score: This factor is designed to quantify the risk of critically ill patients developing adverse events at ICU. It determined with the table(age\_APACHE score\_SOFA score\_ number of co-morbidities\_days from hospital to ICU admission).

#### **Timepoint**

NUTRIC score determination at the beginning of trial(first day) and 8 and 14 days after Formula beginning.

#### **Method of measurement**

NUTRIC score table

## **Secondary outcomes**

### 1

#### **Description**

Side effect: diarrhea/Vomiting/Sensitivity

#### **Timepoint**

Complication incidence at the beginning of trial(first day) and 8 and 14 days after Formula beginning.

#### **Method of measurement**

Patient physical examination

### 2

#### **Description**

Final price of each formula

#### **Timepoint**

end of fourteenth day.

#### **Method of measurement**

Calculation the price of formula

## **Intervention groups**

### 1

#### **Description**

First intervention group: Entera meal standard formula \_ Dose and number of times is due to nutritional need of each patient. Duration of use is 14 days for each patient

#### **Category**

Treatment - Other

### 2

#### **Description**

Second Intervention group: Ensure formula \_ Dose and number of times is due to nutritional need of each patient. Duration of use is 14 days for each patient

#### **Category**

Treatment - Other

### 3

#### **Description**

Control group: Standard gavage of hospital \_ Dose and number of times is due to nutritional need of each patient. Duration of use is 14 days for each patient

#### **Category**

Treatment - Other

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Vali-Asr hospital

##### **Full name of responsible person**

Dr Behnam Mahmodie

##### **Street address**

Vali-Asr hospital., Shahid Shirodi street., Arak

##### **City**

Arak

##### **Province**

Markazi

##### **Postal code**

38149-5-7558

##### **Phone**

+98 86 3222 2003

##### **Fax**

+98 86 2231 2830

##### **Email**

b.mahmudie@arakmu.ac.ir

##### **Web page address**

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Arak University of Medical Sciences

##### **Full name of responsible person**

Dr Mohammad Arjmandzadegan

##### **Street address**

Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak

##### **City**

Arak

##### **Province**

Markazi

##### **Postal code**

848176941

##### **Phone**

+98 86 3417 3645

##### **Fax**

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**Email**

m.arjmandzadegan@arakmu.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Arak University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

Academic

**Person responsible for general inquiries****Contact****Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Shima Shahri

**Position**

Medical student

**Latest degree**

A Level or less

**Other areas of specialty/work**

General Practitioner

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No. 3815163686, nastaran apartment, shahid bazjoo alley, shariati sq, Arak

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sh.shahri@arakmu.ac.ir

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Behnam Mahmoudieh

**Position**

Assistant Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Anesthesiology

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Vali-asr hospital., vali-asr sq., Arak

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**Person responsible for updating data****Contact****Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Shima Shahri

**Position**

Medical student

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A Level or less

**Other areas of specialty/work**

General Practitioner

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**Email**

sh.shahri@arakmu.ac.ir

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

All The data can be shared after personal unidentification

**When the data will become available and for how long**

3 months after Edition of results

**To whom data/document is available**

Researchers-University professors-Students

**Under which criteria data/document could be used**

Do not change The data. Use for new clinical trials.

**From where data/document is obtainable**

Dr Behnam Mahmoudieh b.mahmodie@arakmu.ac.ir

**What processes are involved for a request to access data/document**

Call Dr Mahmoudieh

**Comments**