Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 Commmittee 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
+98 86 3222 2003

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
Street address
No. 3815163686, nastaran apartment, shahid bazjoo alley, shariati sq, Arak
City
Arak
Province
Markazi
Postal code
3815163686
Phone
+98 86 3221 8317
Email
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
Street address
Vali-asr hospital., vali-asr sq., Arak
City
Arak
Province
Markazi
Postal code
38149_5_7558
Phone
+98 86 3222 2003
Fax
Email
b.mahmodie@arakmu.ac.ir

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
Latest degree
A Level or less
Other areas of specialty/work
General Practitioner
Street address
No. 3815163686, nastaran apartment., shahid bazjoo alley., shariati sq., Arak
City
Arak
Province
Markazi
Postal code
3815163686
Phone
+98 86 3221 8317
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