

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Comparison between 4 existing tube feeding formulas in incidence & severity of diarrhea in intensive care unit (ICU) patients .

Protocol summary

Summary

Type of formula is a cause of diarrhea in enterally tube fed patients in ICU. Formulas have been used for enteral fed patients in general & central ICU in Namazi hospital, unfortunately diarrhea have been a major problem with enteral feeding in both ICU due to this main cause increase in hospital cost and length of stay in the ICU. Now there are 4 types available of formulas (Fresubin Original, Ensure powder, Entera meal high fiber, Entera meal standard), so we're going to compare these formulas regarding to incidence & severity of diarrhea. Objectives: 1- the determination of incidence & severity of diarrhea in patients who are fed by Fresubine Original formula. 2- the determination of incidence & severity of diarrhea in patients who are fed by Entera Meal Standard formula. 3- the determination of incidence & severity of diarrhea in patients who are fed by Entera Meal High Fiber formula. 4- the determination of incidence & severity of diarrhea in patients who are fed by Ensure Powder formula. 5- Comparison incidence & severity of diarrhea between 4 formulas. Method: it's a clinical trial study. 128 patients who are admitted in Central & General ICU of Namazi hospital and they don't have renal/liver failure or diabetic, immunocompromised, gastric surgery, drug abuse and they feed by gastric will participated in this study. Data will be collected from initiating NG feeding in ICU patients to maximum 7 days. In advance patient will be entered in groups of formula by Block Randomize method. We will use Harris Benedict method to measure energy expenditure and according to Namazi ICU protocol for advancing patient diet and GRV (Gastric Residual Volume), the amount of formula will increase until achieve goal calorie. For this study, diarrhea was defined as the 'abnormal passage of loose or liquid stools more than three times daily and/or a volume of stool greater than 200 g/day during the patient's ICU admission'. No validated diarrhea measurement tool are used in the ICU at this study. Faecal output was recorded subjectively by nursing staff.

Stool consistency was recorded as formed, semi-formed, loose or watery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201112121566N4**

Registration date: **2012-01-08, 1390/10/18**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-01-08, 1390/10/18

Registrant information

Name

Farid Zand

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1647 4270

Email address

zandf@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

DarmanYab Darou Co. and Jahan Behbood Co.

Expected recruitment start date

2012-02-20, 1390/12/01

Expected recruitment end date

2012-08-20, 1391/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison between 4 existing tube feeding formulas in incidence & severity of diarrhea in intensive care unit (ICU) patients .

Public title
Comparison between 4 existing tube feeding formulas in incidence & severity of diarrhea in intensive care unit (ICU) patients .

Purpose
Prevention

Inclusion/Exclusion criteria
Patients are eligible for inclusion if they: (1) are Nasogastric tube fed via Bolus infusion; (2) ≥18 years of age; and (3) are expected to have an ICU length of stay (LOS) >7days. Participants are excluded from the study if (1) they need special formulas such as diabetic formula , hepatic formula; (2) patients who are immunocompromised, suffered renal /hepatic failure, gastric surgery and post-operative patients; (3) Gastrastomy / Jejunostomy patients ;(4) parenteral nutrition patients ; (5) drug abuse patients; (6) change of feeding to special formula during study and (7) patients who are expected to die < 7 days.

Age
To **100 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **128**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz University of Medical Science

Street address

Namaz Hospital
City
Shiraz
Postal code
Approval date
2011-12-29, 1390/10/08
Ethics committee reference number
CT-90-3709

Health conditions studied

1

Description of health condition studied

Diarrhoea in patients admitted in Intensive Care Unit

ICD-10 code

K59.1

ICD-10 code description

Functional diarrhoea

Primary outcomes

1

Description

Diarrhea Incidence

Timepoint

A week

Method of measurement

Diarrhoea was defined as the 'abnormal passage of loose or liquid stools more than three times daily and/or a volume of stool greater than 200 g/day during the patient's ICU admission' No validated diarrhea measurement tool are used in the ICU at this study. Faecal output was record subjectively by nursing staff. Stool consistency was recorded as formed, semi-formed, loose or watery

Secondary outcomes

1

Description

Percent of calorie intake in first day

Timepoint

One day

Method of measurement

The amount of intake calorie in first day divide total caloric requested for patient multiple 100

2

Description

GI intolerance

Timepoint

Daily for seven days

Method of measurement

Report GRV>250cc every day during 7 days

3

Description

Percent of calorie intake in third day

Timepoint

One day

Method of measurement

The amount of intake calorie in third day divide total caloric requested for patient multiple 100

4

Description

Percent of calorie intake in fourth day

Timepoint

One day

Method of measurement

The amount of intake calorie in fourth day divide total caloric requested for patient multiple 100

5

Description

Percent of caloric intake in second day

Timepoint

One day

Method of measurement

The amount of intake calorie in second day divide total caloric requested for patient multiple 100

6

Description

Percent of caloric intake in fifth day

Timepoint

One day

Method of measurement

The amount of intake calorie in fifth day divide total caloric requested for patient multiple 100

7

Description

Percent of caloric intake in sixth day

Timepoint

One day

Method of measurement

The amount of intake calorie in sixth day divide total caloric requested for patient multiple 100

8

Description

Percent of caloric intake in seventh day

Timepoint

A day

Method of measurement

The amount of intake calorie in seventh day divide total caloric requested for patient multiple 100

9

Description

Nausea& vomiting

Timepoint

Daily for seven days

Method of measurement

Nursing report every days until 7 days

Intervention groups

1

Description

Prescribing Fresubine Original formula as first intervention

Category

Treatment - Other

2

Description

Prescribing "Ensure Powder" formula as second interavention

Category

Treatment - Other

3

Description

Prescribing " Entera Meal Standard" formula as third intervention

Category

Treatment - Other

4

Description

Prescribing " Entera Meal High Fiber" formula as fourth intervention

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Namazi hospital

Full name of responsible person

Dr. Zand

Street address

Namazi Hospital

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

DarmanYab Darou

Full name of responsible person

Dr. Javaheri

Street address

No.32, Soraya Bldg, No. 10, Pardis ST, Mollasadra Ave

, Vanak Sq.

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

DarmanYab Darou

Proportion provided by this source

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

2

Sponsor

Name of organization / entity

Jahan Behbood

Full name of responsible person

Asana Eshghi

Street address

no. 22, Nezam Alley, Shahnazar St , Mohseni Sq.

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Jahan Behbood

Proportion provided by this source

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz University of Medical Science

Full name of responsible person

Fahimeh Edrissi

Position

Nutritionist

Other areas of specialty/work

Street address

#19, no. 46, Alley No. 2/2, Chamran Ave.

City

Shiraz

Postal code

Phone

+98 71 1646 2503

Fax

Email

fahimehed@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Science

Full name of responsible person

Dr. Farid Zand

Position

Associate Professor of Anesthesiology

Other areas of specialty/work

Street address

Department of Anesthesia

City

Shiraz

Postal code

Phone

+98 71 1647 4270

Fax

+98 71 1647 4270

Email

zandf@sums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Science

Full name of responsible person

Fahimeh Edrissi

Position

Nutritionist

Other areas of specialty/work

Street address

Unit 19, No. 46, Alley No. 2/2, Chamran Ave.

City

Shiraz

Postal code

Phone

+98 71 1646 2503

Fax

Email

fahimehed@yahoo.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty