

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jun 2026

Evaluation of the Clinical Signs and symptoms of Pneumonia Following Metoclopramide administration in unconscious patients with nasogastric tube in the intensive care unit.

Protocol summary

Study aim

1. Evaluation of the clinical signs and symptoms of pneumonia following metoclopramide administration in unconscious patients with nasogastric tube (NGT) in the intensive care unit (ICU) 2. Evaluation of the effect of metoclopramide on hospital stay in patients with decreased consciousness and NGT in the ICU. 3. Evaluation of the effect of metoclopramide on the number of days of antibiotic administration in patients with decreased consciousness and NGT in the ICU.

Design

clinical trial (phase 3), Randomized by balanced block randomization and controlled in two parallel groups: intervention group (n = 32) and control group (n = 32).

Settings and conduct

this study will be done in ICU of 5 hospital in Tehran; intervention group will receive tablet of metoclopramide 10 mg 3 times a day for 5 days through nasogastric tube and the control group will not receive placebo. this study will not be blinded.

Participants/Inclusion and exclusion criteria

-inclusion criteria: 1. dysphagia following the loss of consciousness, in ICU patients. 2. Nasogastric tube requirement, more than 24 hours. -exclusion criteria: 1. esophageal disorder. 2. signs and symptoms of pneumonia 3. pregnancy and lactation. 4. history of Parkinson disease. 5. contraindication of metoclopramide. 6. drug interaction with metoclopramide. 7. gastrointestinal disorders like: GI bleeding, obstruction, cancer and perforation. 8. gastrointestinal surgery. 9. pheochromocytoma

Intervention groups

Patients in intervention group (n=32) will have first dose of metoclopramide intravenously, and other doses will be administered of 10 milligram (mg) metoclopramide through the NGT 3 times a day for 5 days. patients in control group will not receive placebo.

Main outcome variables

cough; sputum production; leukocytosis; abnormal signs in chest examination and chest x ray; fever; tachypnoea; hypoxia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160813029327N18**
Registration date: **2019-10-07, 1398/07/15**
Registration timing: **registered_while_recruiting**

Last update: **2019-10-07, 1398/07/15**

Update count: **0**

Registration date

2019-10-07, 1398/07/15

Registrant information

Name

Ramin Abrishami

Name of organization / entity

Islamic Azad University, Pharmaceutical sciences branch

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-20, 1396/12/29

Expected recruitment end date

2020-03-19, 1398/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Clinical Signs and symptoms of Pneumonia Following Metoclopramide administration in unconscious patients with nasogastric tube in the intensive care unit.

Public title

Evaluation of the Clinical Signs and symptoms of Pneumonia Following Metoclopramide administration in unconscious patients with nasogastric tube in the intensive care unit.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

dysphagia following the loss of consciousness, in ICU patients. Nasogastric tube requirement, more than 24 hours.

Exclusion criteria:

oesophageal disorder signs and symptoms of pneumonia pregnancy and lactation history of Parkinson disease contraindication of metoclopramide drug interaction with metoclopramide gastrointestinal disorders like: GI bleeding, obstruction, cancer and perforation, gastrointestinal surgery, presence of pheochromocytoma

Age

From 18 years old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 32

Randomization (investigator's opinion)

Randomized

Randomization description

participants will be recruited to one of the two groups randomly by Balanced block randomization method, and will receive special intervention.

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

Ethics committee of Islamic Azad University of Pharmaceutical Sciences

Street address

Shahid Khaghani street (Zargandeh), Dr Shariati street

City

Tehran

Province

Tehran

Postal code

1916893813

Approval date

2017-12-20, 1396/09/29

Ethics committee reference number

IR.IAU.PS.REC.1396.182

Health conditions studied

1

Description of health condition studied

pneumonia

ICD-10 code

J69.0

ICD-10 code description

Pneumonia due to inhalation of vomit and gastric secretions

Primary outcomes

1

Description

cough incidence

Timepoint

before intervention, day 1, 3 and 5

Method of measurement

observational information and nursing records

2

Description

Tachypnoea (respiratory rate >25 per minute)

Timepoint

before intervention, day 1, 3 and 5

Method of measurement

assessment of vital signs and nursing records

3

Description

- Sputum production or oropharyngeal secretions

Timepoint

before intervention, day 1, 3 and 5

Method of measurement

assessment of clinical situation and nursing records.

4

Description

-Hypoxia (oxygen saturation $\leq 90\%$)

Timepoint

before intervention, day 1,3 and5

Method of measurement

puls oximeter

5

Description

-New abnormal breathing sounds in chest examination

Timepoint

before intervention, day 1,3 and5

Method of measurement

chest physical examination by stethoscope

6

Description

Fever >38 degree celsius

Timepoint

before intervention, day 1,3 and5

Method of measurement

termometer

7

Description

Leucocytosis (WBC $>11\ 000$ per Milliliter)

Timepoint

before intervention, day 1,3 and5

Method of measurement

complete blood count

8

Description

abnormal elevation of erythrocyte sedimentation rate

Timepoint

before intervention, day 1and5

Method of measurement

erythrocyte sedimentation rate test

9

Description

New chest Radiological shadowing

Timepoint

before intervention, day 3 and 5

Method of measurement

chest x ray radiography

10

Description

Leucopenia (WBC < 3000 per Milliliter)

Timepoint

before intervention, day 1,3 and5

Method of measurement

complete blood count

11

Description

abnormal elevation of c reactive protein

Timepoint

before intervention, day 1 and 5

Method of measurement

c reactive protein test

12

Description

Symptom complex of sweating, rigors, fever, and aches and pains

Timepoint

before intervention, day 1,3 and5

Method of measurement

observational information,thermometer and critical care pain observation tool

Secondary outcomes

1

Description

counting the days that patient stays in intensive care unit

Timepoint

from the first day of study to last day of staying patient in the intensive care unit

Method of measurement

assessment of the patients medical records

2

Description

Number of antibiotic therapy days

Timepoint

from the first day of study to last day of staying patient in the intensive care unit

Method of measurement

assessment of the patients medical records

3

Description

Highest white blood cells count in millimeter cube

Timepoint

daily from the first day to 5th day

Method of measurement

complete blood count

4

Description

Highest C reactive protein(milligram per deciliter)

Timepoint

first day and 5th day of study

Method of measurement

c reactive protein assessment test

5

Description

Lowest oxygen saturation percent

Timepoint

daily from the first day to 5th day of study

Method of measurement

puls oxymeter

6

Description

Mortality at 30 days

Timepoint

from the first day of study to 30th day

Method of measurement

assessment of medical records

7

Description

Regurgitation through Nasogastric tube

Timepoint

daily from the first day to 5th day of study

Method of measurement

observational assessment of patients situation

Intervention groups

1

Description

Intervention group: patient receives metoclopramide 10 milligram -three times a day for 5 days.first dose prescribe in form of ampul and should be used from intravenous route.the other doses prescribe in form of tablet and should be used in route of gavage.

Category

Prevention

2

Description

Control group: patients in this group dont receive any drug or interventio n and we just monitor them .

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Booali hospital

Full name of responsible person

Sheyda Khosravi

Street address

Booali hospital, Damavand street, Imam Hossein square

City

Tehran

Province

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1711734365

Phone

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Email

sheydakh@gmail.com

Web page address

<http://bouali.iautmu.ac.ir/fa>

2

Recruitment center

Name of recruitment center

Farhikhtegan hospital

Full name of responsible person

Sheyda Khosravi

Street address

opposite of islamic azad university, university square, end of the north sattari highway

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1477899679

Phone

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Fax

Email

sheydakh@gmail.com

Web page address

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3

Recruitment center

Name of recruitment center

Amiralmomenin hospital

Full name of responsible person

Sheyda Khosravi

Street address

opposite of Sardar Jangal garden,Shirmohammadi street,NaziAbad

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4

Recruitment center

Name of recruitment center

Ghiasi hospital

Full name of responsible person

Sheyda Khosravi

Street addressShahid Soleimani street, Shahid Banaee street, after
Yaft Abad crossroad, Ayatollah Saeedi highway**City**

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Web page address<http://ghiasihospital.com>**5****Recruitment center****Name of recruitment center**

Pasargad hospital

Full name of responsible person

Sheyda Khosravi

Street addressNo. 132, facing Taherian(Amol) sreet, between
Taleghani street and Somayeh street, Shariati street**City**

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1561937114

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Email

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Web page address<http://pasargadgeneralhospital.ir/>**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Islamic Azad University of Pharmaceutical Science

Full name of responsible person

Farshad Hashemian

Street address

#99, Yakhchal Ave, Shariati st.

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Province

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1941933111

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+98 21 2264 0051

Email

Sheydakh@gmail.com

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

Yes

Title of funding source

Islamic Azad University of Pharmaceutical Science

Proportion provided by this source

100

Public or private sector

Private

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**

Islamic Azad University

Full name of responsible person

Mehdi Rajabi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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Islamic Azad University

Full name of responsible person

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Position

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Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Sheyda Khosravi

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Pharmacy Student

Latest degree

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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

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Information about the primary outcome will be shared after Deidentification of Individual Participant Data

When the data will become available and for how long

after publication of paper,for two years

To whom data/document is available

Academic persons

Under which criteria data/document could be used

Academic or clinical use. users should cite the primary document

From where data/document is obtainable

via email to corresponding author

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

Submission of valid and formal documentation of affiliation to the Academic Center, Explanation about how to use the information and the purpose of request

Comments