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 unconsciousness 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 wont 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
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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 histoy 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 especial 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

Ŝhahid 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 and5

Method of measurement

observational information and nursing records

2

Description

Tachypnoea (respiratory rate >25 per minute)

Timepoint

before intervention, day 1,3 and5

Method of measurement

assessment of vital signs and nursing records

3

Description

- Sputum production or oropharyngeal secretions

Timepoint

before intervention, day 1,3 and5

Method of measurement

assessment of clinical situation and nursing records.

4

Description
-Hypoxia (oxygen saturation ≤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 Mililiter)
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
Leucopoenia (WBC < 3000 per Mililiter)
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 paitient 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
Ṡheyda Khosravi
Street address
Booali hospital, Damavand street, Imam Hossein square
City
Tehran
Province
Tehran
Postal code
1711734365
Phone
+98 21 3334 8036
Email
sheydakh@ymail.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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Province
Tehran
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1477899679
Phone
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Fax
Email
sheydakh@ymail.com
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3

Recruitment center
Name of recruitment center
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Full name of responsible person
Sheyda Khosravi
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opposite of Sardar Jangal garden,Shirmohammadi street,NaziAbad
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Fax
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4

Recruitment center
Name of recruitment center
Ghiasi hospital

Full name of responsible person
Sheyda Khosravi
Street address
Shahid Soleimani street, Shahid Banaee street, after Yaft Abad crossroad, Ayatollah Saeedi highway
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5

Recruitment center
Name of recruitment center
Pasargad hospital
Full name of responsible person
Sheyda Khosravi
Street address
No. 132, facing Taherian(Amol) sreet, between Taleghani street and Somayeh street, Shariati street
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Fax
+98 21 7762 2244
Email
sheydakh@ymail.com
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
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#99, Yakhchal Ave, Shariati st.
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1941933111
Phone
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Email
Sheydakh@ymail.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
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1941933111

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Email
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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
Submition of valid and formal documentation of affiliation to the Academic Center, Explaination about how to use the information and the purpose of request

Comments