Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effect of Domperidone in the prevention of pneumonia in patients with stroke

Protocol summary

Study aim

The aim of this study was to evaluate the effect of domperidone on the prevention of pneumonia in patients with stroke.

Design

In this clinical trial, 170 patients with clinical signs and radiological findings of stroke were included in the study. Patients were randomly divided into two groups of 85 patients. The first group received 10 mg of Dopyridone tablets daily and the control group received placebo tablets every 12 hours. The study is a blind study and trial phase 3. Randomization is performed using random sequence generation software. In this way, information such as sample size and number of groups is given to the software and the software provides a table of random numbers, each of which is randomly assigned the letters A and B. In this study, A numbers are in the intervention group and B numbers are in the control group.

Settings and conduct

In this one-way blind clinical trial, 170 patients with clinical signs and radiological findings of stroke in Qazvin Bu Ali Sina Hospital were enrolled. In order to blind the patient, placebo is used instead of dompiridone in the control group and patients do not know about the prescribed drug (placebo and drug).

Participants/Inclusion and exclusion criteria

Inclusion criteria: clinical signs of acute stroke; Radiological findings of acute stroke Exclusion criteria: underlying lung disease; Lung structural disorders; Recent use of prokinetics; Pregnancy; History of previous pneumonia; Immunosuppression.

Intervention groups

One group is given 10 mg of Dopyridone tablets and the other group is given a placebo every 12 hours during the hospital stay.

Main outcome variables

Need for intubation; Duration of hospitalization; Start oral feeding; Nutrition tolerance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201001048896N1**
Registration date: **2020-12-23, 1399/10/03**
Registration timing: **prospective**

Last update: **2020-12-23, 1399/10/03**
Update count: **0**

Registration date

2020-12-23, 1399/10/03

Registrant information

Name
somaieh kiani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 28 3333 2930

Email address
somaiehkiani7@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-04, 1399/10/15

Expected recruitment end date

2021-03-05, 1399/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of Domperidone in the prevention of pneumonia in patients with stroke

Public title
Evaluation of the effect of Domperidone in the prevention of lung infection in patients with stroke
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Clinical signs of acute stroke Radiological findings of acute stroke
Exclusion criteria:
Underlying lung disease Lung structural disorders Recent use of prokinetics Pregnancy History of previous pneumonia Immunosuppression
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **170**
Randomization (investigator's opinion)
Randomized
Randomization description
Due to the ease of use and cost savings in time, participants were divided into two groups using random sequence generation software. In this way, information such as sample size and number of groups is given to the software and the software provides a table of random numbers, each of which is randomly assigned the letters A and B. In this study, A numbers are in the intervention group and B numbers are in the control group.
Blinding (investigator's opinion)
Single blinded
Blinding description
The study was performed blindly. In this study, patients do not know about prescription drugs (placebo and drugs). In order to blind the patient, placebo is used in the control group instead of Dopiridone.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Qazvin University of Medical Sciences
Street address
Vice chancellor for research, Qazvin University of Medical Sciences, Shahid Bahonar blvd
City
Qazvin
Province
Qazvin
Postal code
3415613911
Approval date
2019-12-30, 1398/10/09
Ethics committee reference number
IR.QUMS.REC.1398.258

Health conditions studied

1

Description of health condition studied
Pneumonia
ICD-10 code
J17
ICD-10 code description
Pneumonia in diseases classified elsewhere

Primary outcomes

1

Description
Clinical signs
Timepoint
At admission, 48 hours after taking the drug, at discharge
Method of measurement
Physical examination

Secondary outcomes

1

Description
Requires intubation
Timepoint
Duration of hospitalization
Method of measurement
Physical examination

2

Description
Duration of hospitalization
Timepoint
Patient discharge day
Method of measurement
Physical examination

3

Description
Start feeding orally

Timepoint
During the patient's hospitalization
Method of measurement
Physical examination

4

Description
Nutrition tolerance
Timepoint
During the patient's hospitalization
Method of measurement
Physical examination

Intervention groups

1

Description
Intervention group: Take Dompiridone 10 mg tablet every 12 hours during hospitalization
Category
Treatment - Drugs

2

Description
Control group: Take placebo tablet every 12 hours during hospitalization
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Boo-Ali Hospital
Full name of responsible person
Somaieh Kiani Majd
Street address
Boo-Ali Hospital, Boo-Ali St., Qazvin, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Dr Mohammad Mahdi Emamjomeh
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research.dpt@qums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Qazvin 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
Qazvin University of Medical Sciences
Full name of responsible person
Somaieh Kiani Majd
Position
Resident of Infectious Diseases
Latest degree
Medical doctor
Other areas of specialty/work
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Person responsible for scientific

inquiries

Contact

Name of organization / entity
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Full name of responsible person
Dr Abbas Allami

Position
Professor of Infectious Disease

Latest degree
Specialist

Other areas of specialty/work
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Person responsible for updating data

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Position
Resident of Infectious Diseases

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
No - There is not 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
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
Information is the most commonly used questionnaire, which is a statistical analysis

When the data will become available and for how long
Starting 1 years after publication .

To whom data/document is available
Only available for people working in academic institutions

Under which criteria data/document could be used
Path analysis

From where data/document is obtainable
Dr Somaieh Kiani Majd

What processes are involved for a request to access data/document
The email will be submitted to the project promoter at the discretion of the information.

Comments