

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jun 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 Domperidone 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

Infectious diseases

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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

Contact

Name of organization / entity

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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