

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Aug 2026

Comparison between two protocols of fluid therapy in patients with severe systolic dysfunction and mild diastolic dysfunction

Protocol summary

Study aim

Evaluation the suitable rate of fluid therapy in patients with mild diastolic dysfunction and severe systolic dysfunction

Design

Two arm parallel groups randomised trial on 120 patients with blinded fluid therapy and outcome assessment

Settings and conduct

Patients with severe systolic dysfunction and mild diastolic dysfunction admitted in Boo Ali Sina hospital for coronary angiography are randomised in two groups with different fluid therapy protocols. New pulmonary symptoms and signs will be evaluated after fluid therapy. Patients, research physicians and data analyzers don't know in which group the patients are involved.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with severe systolic dysfunction (LVEF < 30%) and mild diastolic dysfunction
Exclusion criteria: Patients with valvular heart diseases, Patients with pericardial diseases, Patients with infiltrative diseases, Patients with cardiac rhythms other than sinus, Patients with liver diseases, Patients with kidney diseases

Intervention groups

Group 1 with severe systolic dysfunction and mild diastolic dysfunction receive normal saline 1cc/kg/hr over 10 hours
Group 2 with severe systolic dysfunction and mild diastolic dysfunction receive half normal saline 50cc/hr over 10 hours

Main outcome variables

dyspnea; pulmonary rales

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200620047849N1**

Registration date: **2020-06-27, 1399/04/07**

Registration timing: **retrospective**

Last update: **2020-06-27, 1399/04/07**

Update count: **0**

Registration date

2020-06-27, 1399/04/07

Registrant information

Name

Shadi Faghihi Langroudi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3365 2781

Email address

sh.faghihi@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-22, 1397/04/31

Expected recruitment end date

2019-07-22, 1398/04/31

Actual recruitment start date

2018-09-19, 1397/06/28

Actual recruitment end date

2020-02-08, 1398/11/19

Trial completion date

2020-02-08, 1398/11/19

Scientific title

Comparison between two protocols of fluid therapy in patients with severe systolic dysfunction and mild diastolic dysfunction

Public title

Fluid therapy in patients with mild diastolic dysfunction and severe systolic dysfunction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with severe systolic dysfunction(LVEF<30%)

Patients with mild diastolic dysfunction

Exclusion criteria:

Valvular heart diseases Pericardial diseases Heart

rhythm other than sinus rhythm Infiltrative diseases

Kidney disease Liver disease

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **130**

Actual sample size reached: **120**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

In this study, patients, research physician and data analyzers will be unaware of kind of intervention in each group.

Placebo

Used

Assignment

Parallel

Other design features

In this study,the aim group recieved normal saline with rate of 1cc/kg/hr for 10hours and control group recieved half saline with the rate of 50cc/hr for hours.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Qazvin University of Medical Science

Street address

Shahid Beheshti Ave.

City

Qazvin

Province

Qazvin

Postal code

3415613911

Approval date

2018-09-18, 1397/06/27

Ethics committee reference number

IR.QUMS.REC.1397.132

Health conditions studied

1

Description of health condition studied

heart failure

ICD-10 code

I30-I52

ICD-10 code description

Other forms of heart disease

Primary outcomes

1

Description

Dyspnea

Timepoint

Every hour after beginning fluid therapy

Method of measurement

Asking from the patient

2

Description

Pulmonary rales

Timepoint

0,5 ,10 hours after beginning fluid therapy

Method of measurement

Pulmonary Exam

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients with severe systolic dysfunction and mild diastolic dysfunction who receive 1cc/kg/hr normal saline over 10 hours

Category

Treatment - Other

2

Description

Control group: Patients with severe systolic dysfunction and mild diastolic dysfunction who receive 50cc/hr half saline over 10 hours

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Boo Ali Sina Hospital

Full name of responsible person

Zohreh Behnamfar

Street address

Boo Ali Sina Avenue

City

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Qazvin

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3413786165

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+98 28 3333 2930

Fax**Email**

boali.hospital@qums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Seiied Mehdi Mirhashemi

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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

Shadi Faghihi Langroudi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Cardiology

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Person responsible for updating data

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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

Yes - There is 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

Files of statical analyze will be accessible.

When the data will become available and for how long

Data are accessible 10 months after recording the record.

To whom data/document is available

All of research physicians can access the data.

Under which criteria data/document could be used

Data will be accessible for researchers in order to perform future research esand systematic review

From where data/document is obtainable

Dr.Zohreh Behnamfar behnamfarzohreh@gmail.com

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

After receiving the request e_mail ,our colleague,Dr.Z.Behnamfar will send the data as soon as possible.

Comments