

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

Comparing the effect of using furosemide following acetazolamide and hydrochlorothiazide with furosemide and hydrochlorothiazide in treating refractory edema

Protocol summary

Summary

Edema is referred to increase in interstitial fluid that is clinically evident. The main causes of generalized edema are heart failure, renal failure, nephrotic syndrome, glomerulonephritis and chronic liver failure. In some cases, edema is treated by management of the underlying disease. However, in some other cases edema may persist and become more severe that needs adjuvant treatments. Because use of diuretics such as furosemide and hydrochlorothiazide is not completely effective in treating severe refractory edema, use of some other diuretics is also recommended. In this double-blind clinical trial, weight and some lab data including blood urea nitrogen, serum creatinine, serum sodium, serum potassium, serum triglyceride and cholesterol of the 20 random adult patients with nephrotic syndrome who have refractory edema and normal BUN and creatinine and referred to nephrology clinic of Shiraz University of Medical Sciences will be measured; the patients should not have hypokalemia and other causes of edema such as heart failure or cirrhosis. Then the patients are divided into 2 groups with 10 members in each. The first group will be prescribed 40 mg of furosemide and 50 mg of hydrochlorothiazide and the second one will receive 250 mg of acetazolamide and 50 mg of hydrochlorothiazide daily for 1 week. Then, weight and mentioned lab data will be measured again. After that, all the patients will have 40 mg of furosemide daily for 2 weeks. Then, weight and mentioned lab data will be measured for one more time.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014081518798N1**

Registration date: **2014-09-08, 1393/06/17**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-09-08, 1393/06/17

Registrant information

Name

Mohammad Amin Fallahzadeh

Name of organization / entity

Shiraz university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1646 6976

Email address

fallahzadm@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz Nephrourology Research Center

Expected recruitment start date

2014-08-16, 1393/05/25

Expected recruitment end date

2015-01-16, 1393/10/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of using furosemide following acetazolamide and hydrochlorothiazide with furosemide

and hydrochlorothiazide in treating refractory edema

Public title

Role of acetazolamide and hydrochlorothiazide followed by furosemide in treating edema

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: 1. Having refractory edema due to nephrotic syndrome 2. Normal BUN and creatinine 3. Being able to come for weekly visit 4. More than 18 years of age 5. Signing the informed consent form
Exclusion Criteria: 1. Hypokalemia 2. Pregnancy 3. Renal transplant 4. Present malignancy 5. Severe acidosis 6. Using NSAIDs 7. Having another causes of edema including liver cirrhosis, heart failure

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 20

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Department of medical ethics and philosophy of health

Street address

Shiraz Medical School, Zand Avenue, Shiraz, Iran.

City

Shiraz

Postal code

Approval date

2010-08-20, 1389/05/29

Ethics committee reference number

93-01-18-7308

Health conditions studied

1

Description of health condition studied

Refractory edema in nephrotic syndrome

ICD-10 code

N04

ICD-10 code description

Incl.: congenital nephrotic syndrome, lipoid nephrosis

Primary outcomes

1

Description

Weight

Timepoint

3 weeks after the starting the drugs

Method of measurement

Using a scale

Secondary outcomes

1

Description

Blood Urea Nitrogen

Timepoint

3 weeks after starting the drugs

Method of measurement

By laboratory

2

Description

Serum Creatinine

Timepoint

3 weeks after starting the drugs

Method of measurement

By laboratory

3

Description

Serum Sodium

Timepoint

3 weeks after starting the drugs

Method of measurement

By laboratory

4

Description

Serum Potassium

Timepoint

3 weeks after starting the drugs

Method of measurement

By laboratory

5

Description

Serum Triglycerides

Timepoint

3 weeks after starting the drugs

Method of measurement

By laboratory

6

Description

Serum Cholesterol

Timepoint

3 weeks after starting the drugs

Method of measurement

By laboratory

Intervention groups

1

Description

Intervention Arm: Using 250 mg,1 tablet, acetazolamide and 50 mg,1 tablet, hydrochlorothiazide daily for one week followed by 2 weeks use of 40mg ,1 tablet, furosemide daily.

Category

Treatment - Drugs

2

Description

Control Arm: Using 40 mg, 1 tablet, furosemide and 50 mg, 1 tablet, hydrochlorothiazide daily for one week followed by 2 weeks use of 40 mg,1 tablet, furosemide daily.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Motahari Clinic of Shiraz University of Medical Sciences

Full name of responsible person

Mrs. Taghados

Street address

4th floor, Motahari Clinic, Namazi Square, Shiraz, Iran.

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz Nephrourology Research Center

Full name of responsible person

Mahboobe Keshavarzi

Street address

Block 1, 3rd floor, Emam Reza Clinic, Namazee square, Shiraz, Iran.

City

Shiraz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shiraz Nephrourology Research Center

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz Medical School

Full name of responsible person

Mohammad Amin Fallahzadeh

Position

Medical Student

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

Mohammad Mehdi Sagheb

Position

Subspecialist of adult nephrology

Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty