

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

The effectiveness of N-acetylcysteine (NAC) on accelerating renal failure recovery in patient with leptospirosis in Razi Hospital of Ghaemshahr city 2019

Protocol summary

Study aim

The effectiveness of N-acetylcysteine (NAC) on accelerating renal failure recovery in patient with leptospirosis

Design

This study is a two-course clinical and two stage chromosomal trauma that will be performed in a group of 32 patient referred to Razi Hospital in Ghaemshahr.

Settings and conduct

In this study 64 patients with leptospirosis who had acute renal failure at the same time were randomly assigned to two equal groups receiving routine treatments and the N-acetylcysteine receiving group will be divided this study will be a double blind study in which the patient will be the final evaluator of the type of study to be blinded the study population will be people with leptospirosis referred to Razi Hospital in Ghaemshahr who have reached definitive diagnosis based on Microscopic Agglutination Test (MAT) and Enzym-Linked Immunosorbent Assay (ELISA)

Participants/inclusion and exclusion criteria

Inclusion criteria: people with leptospirosis who have been diagnosed with ELISA with MAT and have a GFR of less than 60 and consent to participate in the study
No entry criteria: people with diabetes, people with underlying liver disease, people with underlying kidney disease and patient who have been hospitalized with sepsis symptoms prior to referral

Intervention groups

N-acetylcysteine tablet intervention group 1200 mg is taken orally every 12 hours for 48 hours and the control group also receives the usual treatment

Main outcome variables

Accelerate the improvement of renal function in leptospirosis patients and improve laboratory indicators of renal function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190727044343N4**

Registration date: **2020-07-28, 1399/05/07**

Registration timing: **retrospective**

Last update: **2020-07-28, 1399/05/07**

Update count: **0**

Registration date

2020-07-28, 1399/05/07

Registrant information

Name

Lotfollah Davoodi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 4221 8231

Email address

lotfdavoodi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-05, 1398/02/15

Expected recruitment end date

2020-05-20, 1399/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of N-acetylcysteine (NAC) on accelerating renal failure recovery in patient with leptospirosis in Razi Hospital of Ghaemshahr city 2019

Public title

The effectiveness of N-acetylcystein (NAC) on accelerating renal failure recovery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

People with Glomerular Filtration Rate (GFR) have less than 60 studies. People whose leptospirosis has been confirmed by Enzym-Linked Immunosorbent Assay (ELISA) or Microscopic Agglutination Test (MAT) .

Satisfaction to participate in the study.

Exclusion criteria:

Diabetics are excluded from the study. People with underlying liver disease are excluded from the study. People with underlying kidney disease excluded from the study. Patients who have been hospitalized with sepsis symptoms prior to referral.

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: 64

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study patient are divided in to two group of 32 people both of whom receive the usual treatments and the intervention group also receives N-acetylcysteine in addition to the usual therapies. Allocation of even and odd numbers to them is according to the time of hospitalization and the researcher have no information about which patients receive N-acetylcysteine and are given by the nurse. And the patient and the final evaluator will be blind towards study allocation.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mazandaran University of Medical Sciences

Street address

Moallem

City

Sari

Province

Mazandaran

Postal code

4817844718

Approval date

2020-02-26, 1398/12/07

Ethics committee reference number

IR.MAZUMS.REC.1398.1392

Health conditions studied

1

Description of health condition studied

Leptospirosis - Acute renal failure

ICD-10 code

A27

ICD-10 code description

Leptospirosis

Primary outcomes

1

Description

Decreased mean serum creatinine levels.

Timepoint

Measurement of serum creatinine levels on days 0,3 and 7 after initiation of treatment.

Method of measurement

Blood serum sample

Secondary outcomes

1

Description

Improved glomerular filtration rate

Timepoint

0,3and days to start treatment.

Method of measurement

Blood serum sample

Intervention groups

1

Description

Intervention group:The group to individual number is

assigned is treated with N-acetylcystein 1200mg every 12 hours for 48 hours po. Pharmaceutical production is Osvah

Category

Treatment - Drugs

2

Description

Control group: The group to which the even number are assigned receives routine appointments.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center**Name of recruitment center**

Razi hospital

Full name of responsible person

Lotfollah Davoodi

Street address

Ghaemshahr razi hospital

City

Ghaemshahr

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Mazandaran

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4765686143

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Email

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Mazandaran 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**

Mazandaran University of Medical Sciences

Full name of responsible person

Lotfollah Davoodi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be 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