Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jun 2026

The effect of routine rhabdomyolysis treatment with and without concomitant administration of Montelukast on the stop progression and recovery time of rhabdomyolysis

Protocol summary

Study aim

Determining the effect of routine rhabdomyolysis treatment with and without concomitant administration of Montelukast on rhabdomyolysis recovery or stop progression in patients of Poisoned ward of Tehran Loghman-Hakim Hospital.

Design

Clinical trial with control group with parallel groups of phase 1 randomized blind blind on 60 patients. Rand function of Excel software was used for randomization.

Settings and conduct

Patients with rhabdomyolysis (CPK> 1000) will be selected in the poison ward of Loghman-Hakim Hospital in Tehran and will be written in order, and odd numbers will be included in the control group and even numbers will be included in the target group.Control group Will receive routine treatment of rhabdomyolysis by hydration,bicarbinate and placebo but the target group will receive routine treatment and oral Montelukast or gavage at a dose of 10 mg twice daily.Daily check of CPK and Cr enzymes and comparison of increasing or decreasing changes and decreasing or ascending course of the above enzymes in the two groups and examining the results of these changes and the significance or not of these statistics in the effectiveness of concomitant administration of Montelukast in rhabdomyolysis will be evaluated and concluded. Was

Participants/Inclusion and exclusion criteria

Patients who admitted to the Poison ward of Loghman-Hakim Hospital who have suffered from rhabdomyolysis and do not have kidney disease or diabetes

Intervention groups

Poisoned patients with rhabdomyolysis(cpk> 1000) are divided into control and target groups and the control group is treated only with hydration, bicarbonate and placebo, but in addition to the above treatment, Montelukast is also prescribed to the target group.

Main outcome variables

The rate of decline of rhabdomyolysis. Reduce cpk

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210720051946N2**
Registration date: **2022-05-19, 1401/02/29**
Registration timing: **prospective**

Last update: **2022-05-19, 1401/02/29**
Update count: **0**

Registration date

2022-05-19, 1401/02/29

Registrant information

Name

Peyman Erfan Talab Evini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5102 5000

Email address

peyman1346erfan@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-22, 1401/03/01

Expected recruitment end date

2022-06-10, 1401/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of routine rhabdomyolysis treatment with and without concomitant administration of Montelukast on the stop progression and recovery time of rhabdomyolysis

Public title

The effect of Montelukast administration on rhabdomyolysis state

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients that admit with drug or substance toxicity and progress to rhabdomyolysis

Exclusion criteria:

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Through the table of numbers: 60 patients who have enough criteria for participation in this plan are written from number one to 60 then even numbers enter the intervention group and odd numbers enter the control group.

Blinding (investigator's opinion)

Single blinded

Blinding description

For this study, patients with rhabdomyolysis (CPK> 1000) was selected from poisoning ward at Loghman Hakim Hospital in Tehran and divided into control and target groups: 1-Control group will receive routine rhabdomyolysis treatment by hydration therapy and bicarbonate therapy 2- Target group will receive hydration therapy with oral Montelukast or gavage at a dose of 10 mg twice daily. In this study, patients or their companions who enter the study are given consent to prescribe a new drug, but the control and target groups remain unaware of the type of treatment received and are kept blind.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Aarabi Ave.,Velenjak.,Tehran City

City

Tehran

Province

Tehran

Postal code

1333635445

Approval date

2021-06-22, 1400/04/01

Ethics committee reference number

IR.SBMU.RETECH.REC.1400.441

Health conditions studied

1

Description of health condition studied

Rhabdomyolysis

ICD-10 code

M62.82

ICD-10 code description

Rhabdomyolysis

Primary outcomes

1

Description

Cpk

Timepoint

Daily

Method of measurement

Labratory

Secondary outcomes

empty

Intervention groups

1

Description

Control group:Includes odd numbers in the numbered list of patients undergoing routine rhabdomyolysis (24-hour maintenance fluid therapy plus one liter of Normal saline per 1000 units of Cpk increase above 1000) while maximal normal saline is added intake is 4 liters in 24 hours. In cases of Cpk> 5000 , patients will receive only

an infusion of 200 cc of 5% dextrose serum with 30 milliequivalents of Sodium bicarbonate per hour.Nephrology consultation will be performed for all patients and according to the Nephrologist, the patients who are candidates for dialysis for any reason will be removed from the plan and another patient will be replaced.

Category

N/A

2

Description

Intervention group: Includes even numbers in the numbered list of patients receiving treatment in the control group, but in addition, Montelukast tablets are taken as 10 mg every 12 hours orally or by gavage until the Cpk is reduced to less than 1000. This group patients, like the control group, if for any reason, according to the Nephrologist, are candidates for dialysis, they will be excluded from the plan and another patient will be replaced.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Poisoned ward of Loghman-Hakim hospital
Full name of responsible person
Peyman Erfantalab Avini
Street address
Special street., Loghman Hakim Hospital
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Tehran
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarbi
Street address
No. 2, Shahid Aarabi St.,, Yemen St., Shahid Chamran Highway., Tehran city
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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

Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Peyman Erfantalab Avini
Position
Assistant Professor
Latest degree
Subspecialist
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)
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
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Data are age, sex, and test results of the control and target groups, and only part of the data can be shared
When the data will become available and for how long
Access will start from the time the results are printed
To whom data/document is available
Everyone
Under which criteria data/document could be used
Allowed for scientific and medical uses
From where data/document is obtainable
Email:peyman1346erfan@sbmu.ac.ir
What processes are involved for a request to access data/document
Email:peyman1346erfan@sbmu.ac.ir The applicant states the reason for her request by sending her request to the above email, and then within about two weeks, the general information of the patients without mentioning their names and details and the results of this research will be sent to him.
Comments