

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

considering effect of serum with bicarbonate and serum without bicarbonate with sodium in treatment of hemolysis caused by glucose 6-phosphate dehydrogenase deficiency

Protocol summary

2013-04-21, 1392/02/01

Summary

Objective of this proposal is evaluation of possible side effects of sodium bicarbonate and its effect in treatment of Hemolytic anemia due to G6PD deficiency. Inclusion criteria are just diagnosis favism. Beans consumption and highlighted in urine are the first items for diagnosis of favism and it is confirmed by urinalysis that is hemoglobinuria positive. Exclusion criteria are dissatisfaction. All of people admitted to emergency department of Taleghani hospital in determined time and with favism will be studied. There are not any special age ranges. After evaluation of clinical and paraclinical factors, patients will be divided in 3 groups: 1) in hemoglobin <7 g/dl, patient will receive packed cell and treat by serum with bicarbonate or serum without bicarbonate and with sodium randomly; 2) in hemoglobin 7-9 g/dl, with hemoglobinuria, will be done like previous protocol and without hemoglobinuria, the patient is hospitalized for 24 hours. After backing to 1 or 2 situation, will be done according to determined protocol; and 3) in hemoglobin >9 g/dl and with hemoglobinuria, will be done according to this method and without hemoglobinuria, patient will be excluded. The clinical and paraclinical factors will be evaluated again before discharge.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013031012765N1**
Registration date: **2013-04-21, 1392/02/01**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

Registrant information

Name

Azam Rashidbaghan

Name of organization / entity

Golestan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and Technology, Golestan University of Medical Sciences

Expected recruitment start date

2013-03-21, 1392/01/01

Expected recruitment end date

2017-03-19, 1395/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

considering effect of serum with bicarbonate and serum without bicarbonate with sodium in treatment of hemolysis caused by glucose 6-phosphate dehydrogenase deficiency

Public title

Comparison efficacy of tow serum therapy methods (serum with bicarbonate and without bicarbonate with

sodium) in some factors (creatinin, pH of urine, term negative UA in terms of hemoglobin and granular casts) patients with hemolysis caused by glucose 6-phosphate dehydrogenase enzyme deficiency in Taleghani hospital, Gorgan

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria is just diagnosis favism. Beans consumption and Highlighted in urine are the first items for diagnosis of favism and it is confirmed by urinalysis that is Hemoglobinuria positive. Exclusion criteria is dissatisfaction.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 70

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Golestan University of Medical Sciences

Street address

Falsafi Higher Education Bilding, Bigining of Shatkola Roade

City

Gorgan

Postal code

Approval date

2013-02-13, 1391/11/25

Ethics committee reference number

29451391112921

Health conditions studied

1

Description of health condition studied

hemolysis due to glucose 6-phosphate deficiency

ICD-10 code

D55.0

ICD-10 code description

Anaemia due to glucose-6-phosphate dehydrogenase [G6PD] deficiency

Primary outcomes

1

Description

hemoglpbine

Timepoint

befor intevention and after intervention, befor discharge

Method of measurement

g/dl- according to tests

2

Description

creatinine

Timepoint

befor intevention and after intervention, befor discharge

Method of measurement

mg/dl- according to tests

3

Description

pH of urine

Timepoint

befor intevention and after intervention, befor discharge

Method of measurement

by pH meter

4

Description

UA-cast

Timepoint

befor intevention and after intervention, befor discharge

Method of measurement

BY Urinalysis

Secondary outcomes

1

Description

Time of admission until discharge

Timepoint

at discharge

Method of measurement

Measuring the time from the moment of admission to hospital discharge

2

Description

number of blood transfusion
Timepoint
during treatment
Method of measurement
The frequency of blood transfusion

3

Description
Blood volume injected for each time
Timepoint
during intervention
Method of measurement
ml- Based on the amount of blood recieved at every turn

4

Description
Time to clear urine
Timepoint
at the end of intervention
Method of measurement
being negative urine from hemoglobinuria

5

Description
side effects of ficarbonate
Timepoint
after intervention
Method of measurement
basis on observed side effects

Intervention groups

1

Description
treatment by serum with bicarbonate, 1.5 times of
Maintaining serum volume of dextrose water 5% and for
100 milliliter, 3 meq/lit of bicarbonate
Category
Treatment - Drugs

2

Description
treatment by serum with bicarbonate, 1.5 times of
Maintaining serum volume of dextrose water 5% and for
100 milliliter, 3 meq/lit of NaCl.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Hematology and Oncology Research Center
Full name of responsible person
Narges beigom Mirbehbahani

Street address
Taleghani Hospital, Janbazan Boulevard
City
Gorgan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research and Technology-
Golestan University of Medical Sciences
Full name of responsible person
Dr. Mohammad Jfar Golalipour
Street address
Falsafi Higher Education Bilding, Bigining of Shastkola
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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
Vice Chancellor for Research and Technology- Golestan
University of Medical Sciences
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
Hematology & Oncology Research Center, Golestan
University of Medical Sciences
Full name of responsible person
Narges beigom Mirbehbahani, Skineh Mohammadian
Position
Associate Professor , Associate Professor
Other areas of specialty/work
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Person responsible for scientific inquiries

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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