

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

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

#### Protocol summary

##### 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

2013-04-21, 1392/02/01

##### Registrant information

###### Name

Azam Rashidbaghan

###### Name of organization / entity

Golestan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 17 1232 8539

###### Email address

hocr@goums.ac.ir

##### 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 soduim 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  
roade  
**City**  
Gorgan  
**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

### Contact

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Hematology and Oncology Research Center, Golestan  
University of Medical Sciences

**Full name of responsible person**

Azam Rashibaghan

**Position**

MSc./ research expert of Hematology and Oncology  
Research Center

**Other areas of specialty/work**

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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*