

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Comparison of the frequency of acute hemolysis induced nephropathy in patients with glucose 6 phosphate dehydrogenase deficiency treated with 3 different therapeutic fluid treatments

Protocol summary

Study aim

The aim of this study is to determine the frequency of nephropathy-induced by acute hemolysis in patients with glucose-6-phosphate dehydrogenase deficiency treated with 3 different fluid therapy methods.

Design

A clinical trial with a control group, with parallel-group, randomized, 132 patients, phase 3

Settings and conduct

In this randomized double-blind clinical trial study, infants and children aged 3 months to 18 years with acute hemolysis due to G6PD deficiency admitted to Shahrivar Hospital in Rasht in 1398 requiring at least 24 hours fluid therapy and hospitalization for follow-up will be studying for 24 to 72 hours.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 3 months to 18 years, urinary hemoglobin more or equal to + 2, need to receive intravenous fluids for at least 24 hours, acute hemolysis caused by favism or G6PD deficiency, hospitalization for 24 to 72 hours Exclusion criteria: Patients will be excluded if any of the following adverse events occur: sodium levels below 130 and above 150, neurological symptoms of hyponatremia, symptoms of fluid retention and general puffiness, Oligo Anuric renal failure

Intervention groups

Intervention group 1: Receiving 1.5 folds of maintenance normal saline serum which will be continued until discharge, Intervention group 2: Receiving 1.5 folds of maintenance half saline which will be continued until discharge + 7 cc bicarbonate/liter, Intervention group 3: Receiving 1.5 folds of maintenance normal saline which will be continued until discharge + 5 mg/ kg/ day Acetazolamide for 48 hours

Main outcome variables

The Frequency of Nephropathy due to Acute Hemolysis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090111001545N5**

Registration date: **2020-03-03, 1398/12/13**

Registration timing: **registered_while_recruiting**

Last update: **2020-03-03, 1398/12/13**

Update count: **0**

Registration date

2020-03-03, 1398/12/13

Registrant information

Name

Hamidreza Badeli

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 1322 9523

Email address

badeli@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-09, 1398/01/20

Expected recruitment end date

2020-06-20, 1399/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the frequency of acute hemolysis induced nephropathy in patients with glucose 6 phosphate dehydrogenase deficiency treated with 3 different therapeutic fluid treatments

Public title

Comparison of the frequency of acute hemolysis induced nephropathy in patients with glucose 6 phosphate dehydrogenase deficiency treated with 3 different therapeutic fluid treatments

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

age : 3 months - 18 years old hemoglobinuria $\geq 2+$ intra venous fluid therapy for at least 24 hours acute hemolysis induced Favism or glucose 6 phosphate dehydrogenase deficiency hospitalization for 24 to 72 hours

Exclusion criteria:

Presence of Dysatremia Central Diabetes insipidus or renal Diabetes insipidus Barrett's Syndrome Nephrotic Syndrome Chronic Kidney Disease Congestive heart failure Liver cirrhosis Metabolic diseases Diabetic ketoacidosis Congenital adrenal hypoplasia shock Glaucoma Addison's disease Unwilling to participate

Age

From **3 months** old to **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **132**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: Simple randomization, randomization unit: individual, randomization tool: random number table Patients who met the inclusion criteria were selected by a random number table from left to right reading method. The numbers were between 00 and 44 in group 1 and patients with numbers between 44 and 88 in group 2 and patients with numbers from 88 to 132 were divided into group 3.

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 Guilan University of Medical Sciences

Street address

Shahid Siadati

City

Rasht

Province

Guilan

Postal code

4144654679

Approval date

2019-04-13, 1398/01/24

Ethics committee reference number

IR.GUMS.REC.1398.026

Health conditions studied

1

Description of health condition studied

Glucose 6 Phosphate Dehydrogenase Deficiency

ICD-10 code

D55.0

ICD-10 code description

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

Primary outcomes

1

Description

The Frequency of Nephropathy due to Acute Hemolysis

Timepoint

Assessing the frequency of Nephropathy before intervention and 6, 12, 24, 48, and 72 hours after intervention

Method of measurement

Laboratory examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Receiving 1.5 folds of maintenance normal saline serum which will be continued until discharge, Intervention group 2: Receiving 1.5 folds of maintenance half saline which will be continued until discharge + 7 cc bicarbonate/liter, Intervention group 3: Receiving 1.5 folds of maintenance normal saline which will be continued until discharge + 5 mg/ kg/ day

Acetazolamide for 48 hours

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

17-Shahrivar Children Hospital

Full name of responsible person

Hamidreza Badeli

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Siadati St

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Shadman Nemati

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Grant name

Grant code / Reference number

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

No

Title of funding source

Vice Chancellor of Reserach- Guilan 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

Rasht University of Medical Sciences

Full name of responsible person

Hamidreza Badeli

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Person responsible for updating data

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Position

Nephrologist and Associate Professor of Guilan
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Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Regarding the ethical issues and confidentiality

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available