

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The Effects of Vitamin E And Folic Acid on The improvement of acute hemolysis Due of deficient G6PD on the children refer to the 17th Shahrivar hospital in Rasht, 2014.

Protocol summary

Summary

The aim of this study is to assess the Efficacy of Vitamin E And Folic Acid on the improvement of acute hemolysis Due of deficient G6PD on the children refer to the 17th Shahrivar hospital in Rasht, 2014. patients are children aged 1-14 years which referred to 17 shahrivar hospital during 2014-2015. G6PD deficient children with hemolytic anemia consequent to acute phase will be included. 120 patients will be entered in 4 parallel groups with the same sample size. first group (100 mg vitamin E for children aged 1-2 years, 200 mg for children aged 2-3 years, 300 mg for children aged 3-4 years and 400 mg for children aged more than 4 years) second group (daily acid folic ,200 mg for children aged 1-2 years and 5 mg for children aged more than 2 years) third group used vitamin E and folic acid for 2 weeks forth group received no drug. (control group) the level of hemoglobin and the percentage of reticulocyte will be measured before intervention and 2 weeks after the initiation of intervention. if patients need blood transfusion, the volume of infused blood and the number of infusions will be registered for each patient.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014102019541N1**
Registration date: **2014-11-04, 1393/08/13**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-11-04, 1393/08/13

Registrant information

Name

Adel Baghersalimi

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 3332 6101

Email address

baghersalimi498@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

The Deputy of Research of Guilan University Of Medical Sciences

Expected recruitment start date

2014-05-22, 1393/03/01

Expected recruitment end date

2015-05-22, 1394/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effects of Vitamin E And Folic Acid on The improvement of acute hemolysis Due of deficient G6PD on the children refer to the 17th Shahrivar hospital in Rasht, 2014.

Public title

The Effects of Vitamin E And Folic Acid on The improvement of acute hemolysis Due of deficient G6PD on the children refer to the 17th Shahrivar hospital in Rasht, 2014.

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion criteria : age: 1-14 yeasers; G6PD deficient children; acutephase hemolysis; no use of vitamine E or folic acid during past 1 months. exclusion criteria : no referal for followup labaratory examinations; death before the end of the study; hemolysis consequent to other causes exept G6PD deiciency

Age
From **1 year** old to **14 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **120**

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

The Deputy of Research of Guilan University of Medical Sciences

Street address

Gaz Square

City

Rasht

Postal code

Approval date

2014-09-16, 1393/06/25

Ethics committee reference number

1930309902

Health conditions studied

1

Description of health condition studied

Glucose 6 Phosphate Dehydrogenase Deficiency

ICD-10 code

D55.0

ICD-10 code description

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

Primary outcomes

1

Description

The level of Hemoglobine

Timepoint

Before Intervention and 2 Weeks after the initiation of intervention

Method of measurement

Based on gram per deciliter with the complete bloodcells count examination

Secondary outcomes

1

Description

assessing the level of reticulocyte

Timepoint

before interventions and 2 weeks after the initiation of intervention

Method of measurement

the percentage of reticulocytes derived from complete bloodcells count

Intervention groups

1

Description

first group(100 mg vitamin E for children aged 1-2 years, 200 mg for children aged 2-3 years, 300 mg for children aged 3-4 years and 400 mg for children aged more than 4 years) 2 weeks, oral

Category

Treatment - Drugs

2

Description

Third group 100 mg vitamin E for children aged 1-2 years, 200 mg for children aged 2-3 years, 300 mg for children aged 3-4 years and 400 mg for children aged more than 4 years and 2mg folic acid daily for children aged 1-2 years and 5 mg folic acid daily for children aged more than 2 years. 2 Weeks oral

Category

Treatment - Drugs

3

Description

Second group 2mg folic acid daily for children aged 1-2 years and 5 mg folic acid daily for children aged more than 2 years. 2 Weeks oral

Category

Treatment - Drugs

4

Description

control group: no treatment will be administered

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

17 shahrivar hospital

Full name of responsible person

Dr Adel Baghersalimi

Street address

17 Shahrivar Hospital, Shahid Siadati Street

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

TeDdeputy of Research of Guilan University of Medical Sciences

Full name of responsible person

Dr Abtin Heidarzadeh

Street address

Gaz Square

City

Rasht

Grant name

Grant code / Reference number

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

Yes

Title of funding source

TeDdeputy of Research of Guilan 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

Guilan University Of Medical Sciences

Full name of responsible person

Dr Adel Baghersalimi

Position

Peciaric Hematologist and Oncologist Assistant Professor

Other areas of specialty/work

Street address

17 Shahrivar Hospital , Hematology Ward

City

Rasht

Postal code

Phone

+98 13 3332 6101

Fax

Email

baghersalimi498@gums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Guilan University of Medical Sciences

Full name of responsible person

Dr Adel Baghersalimi

Position

Pediatric Hematologist Oncologist Assistant Professor

Other areas of specialty/work

Street address

17 Shahrivar Hospital

City

Rasht

Postal code

Phone

+98 13 3332 6101

Fax

Email

baghersalimi498@gums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Guilan University of Medical sciences

Full name of responsible person

Dr Sharareh Zarezadeh

Position

medical resident

Other areas of specialty/work

Street address

17 Shahrivar Hospital, Shahid Siadati Square

City

Rasht

Postal code

Phone

+98 33326101

Fax

Email

dr.zarezadeh@yahoo.com

Web page address

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