Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The efficiency of recombinant human erythropoietin in reducing the need for blood transfusions in patients with solid tumors receiving chemotherapy.

Protocol summary

Summary

Objectives: evaluating the consumption of human recombinant Erythropietin in anemic patients diagnosed with solid insitu tumor to reduce the need for blood transfusions and referring to clinic Design:Population being studied: hospitalised patients in the Hematology ward with solid insitu tumor,the volume of the sample:60 patients, randomized controlled trial,not blinded,one-centered Setting and conduct: Sixty hospitalised patients in the Hematology ward with solid insitu tumor were divided into 2 case and control groups. Patients in case group-including 30 patients-will receive Erythropoietin 450 IU/kg subcutaneously once in a week,for 12 weeks. Main inclusion criteria: hospitalised patients in the Hematology ward beneath 15 years of age,with solid insitu tumor and no bone marrow involvement Main exclusion criteria: Erythropoietin side effects The intervention being studied: Using human recombinant Erythropoietin Duration of intervention:1 year Primary outcome measures:Increase in Hemoglobin, the numbers and volume of blood transfusions Secondary outcome measures:the numbers of referring to the clinic

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015061822805N1**
Registration date: **2015-08-22, 1394/05/31**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-08-22, 1394/05/31

Registrant information

Name

Amir Ataollah Hiradfar

Name of organization / entity

Pediatric Health Research Center, Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 3526 2251

Email address

hiradfara@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Tabriz University of Medical Sciences

Expected recruitment start date

2014-04-21, 1393/02/01

Expected recruitment end date

2015-07-23, 1394/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The efficiency of recombinant human erythropoietin in reducing the need for blood transfusions in patients with solid tumors receiving chemotherapy.

Public title

The benefits of Erythropoietin in reducing the need for blood transfusions in patients receiving chemotherapy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Age of the patients, entering the study, should be beneath 15 years; The amount of Hemoglobin should be below 10 g/dL(gram per deciliter); Patients who are anemic due to chemotherapy, after they are diagnosed with solid insitu tumor; None of the patients have bone marrow involvement; Patients entering the study have normal kidney,liver,and lung function; Normal amounts of other blood-related parameters including retic.count, Serum ferritin, B12 vitamin in the serum, direct and indirect coombs tests, and ABG(Arterial Blood Gas); No history of blood transfusions in the last 1 month; No history of Erythropoietin consumption
Exclusion criteria: Severe bleeding during the study; Hemolysis during the study due to any causes; The evidence of existing imapirment in kidney,liver,and lung function; Evidence of any serious side effects of Erythropoietin including thrombosis, increased systemic blood pressure, and polycythemia

Age
From **1 year** old to **15 years** old

Gender
Both

Phase
1-2

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Randomization was carried out by the random numbers chart.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences

Street address
Research and Technology deputy, third floor, central building number 2, Tabriz University of Medical Sciences,Golgasht street

City
Tabriz

Postal code

Approval date
2015-05-25, 1394/03/04

Ethics committee reference number
tbzmed.rec.1394.164

Health conditions studied

1

Description of health condition studied
solid insitu tumor of the body

ICD-10 code
D00-D09

ICD-10 code description
In situ neoplasms

Primary outcomes

1

Description
The amount of hemoglobin increase

Timepoint
Weekly, until the end of the treatment

Method of measurement
g/dL(gram per deciliter) in blood tests

2

Description
The numbers and volume of blood transfusions

Timepoint
weekly blood test(hemoglobin amounts;transfusion of 10 ml/kg when hemoglobin is under 7 ml/dl)

Method of measurement
Based on patients' hemoglobin and in mililiter

Secondary outcomes

1

Description
the numbers of referring to the clinic

Timepoint
weekly

Method of measurement
using their clinic files

Intervention groups

1

Description
Control group: Patients who receive only common chemotherapy agents without human recombinant Erythropoietin

Category
Treatment - Drugs

2

Description

Intervention group: Anemic patients due to chemotherapy, receiving human recombinant Erythropoietin,450 units per kilogram, Subcutaneously once in week for 12 weeks Manufacturer company: Pooyesh Darou Biopharmaceutical co.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Children's hospital

Full name of responsible person

Amir Ataollah Hiradfar

Street address

Children's hospital, Sheshgelan street

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Tabriz University of Medical Sciences

Full name of responsible person

Amir Ataollah Hiradfar

Street address

Central building of Tabriz University of Medical Sciences, Golgasht street, Azadi street

City

Tabriz

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 of Tabriz 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

Pediatric Health Research Center, Tabriz University of Medical Sciences

Full name of responsible person

Amir ataollah hiradfar

Position

Pediatrician,Subspecialist in Hematology and Oncology

Other areas of specialty/work

Street address

Children's hospital, Sheshgelan street

City

Tabriz

Postal code

Phone

+98 41 3526 2265

Fax

+98 41 3526 2265

Email

hiradfarataollah@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Pediatric Health Research Center, Tabriz University of Medical Sciences

Full name of responsible person

Amir Ataollah Hiradfar

Position

Pediatrician, Subspecialist in Hematology and Oncology

Other areas of specialty/work

Street address

Children's hospital, Sheshgelan street

City

Tabriz

Postal code

Phone

+98 41 3526 2265

Fax

Email

hiradfarataollah@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Pediatric Health Research Center, Tabriz University of Medical Sciences

Full name of responsible person

Amir Ataollah Hiradfar

Position

Pediatrician,Subspecialist in Hematology and Oncology

Other areas of specialty/work

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Fax
Email
hiradfarataollah@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