Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Comparison of the effect of prophylactic granulocyte colony-stimulating factor versus placebo on neutrophil count before chemotherapy on children with malignant neuroblastoma

Protocol summary

Summary

Background and Objectives: the aim of this study is the valuation of prophylactic granulocyte colony-stimulating factor before chemotherapy on children's with malignant neuroblastoma; Major inclusion and exclusion criteria: patients with pathologically confirmed neuroblastoma, stage 3 and 4 of disease, normal cell counts before each cycle of chemotherapy, absolute neutrophil count above 1000 and platelet count above 100000 per cubic microliter will be enrolled into the study and patients with previous history of receiving granulocyte colony stimulating factor will be excluded from the study. Study population and size; a number of 50 children with malignant neuroblastoma will randomly be assigned into two equal intervention and control groups. Interventions and major outcomes: we use granulocyte stimulating factor for intervention group three times prior to the chemotherapy for the intervention group and three times of placebo three times prior to the chemotherapy for the control group, the major final outcome is the increased neutrophil count in complete blood count after three days of chemotherapy.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014050717610N1**
Registration date: **2014-09-27, 1393/07/05**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-09-27, 1393/07/05

Registrant information

Name
Azim Rezamand
Name of organization / entity
Tabriz University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 41 1334 2299
Email address
rezamand@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2014-02-20, 1392/12/01

Expected recruitment end date

2014-09-21, 1393/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of prophylactic granulocyte colony-stimulating factor versus placebo on neutrophil count before chemotherapy on children with malignant neuroblastoma

Public title

Evaluation of prophylactic granulocyte colony-stimulating factor before chemotherapy on children's with malignant neuroblastoma

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: pathologically confirmed neuroblastoma; age below 16 years; stage 3 and 4 of disease; normal cell counts before each cycle of chemotherapy; absolute neutrophil count above 1000 and platelet count above 100000 per cubic microliter Exclusion Criteria: previous history of receiving granulocyte colony stimulating factor

Age
From **6 months** old to **15 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

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

Street address
Central Building of Tabriz University of Medical Sciences, Golgasht avenue, Azadi street, Tabriz, Iran

City
Tabriz

Postal code

Approval date
2014-02-12, 1392/11/23

Ethics committee reference number
5/4/10440

Health conditions studied

1

Description of health condition studied
malignant noroblastoma

ICD-10 code
C74.9

ICD-10 code description
Adrenal gland, unspecified

Primary outcomes

1

Description
Increased numbers of neutrophils

Timepoint
3 days

Method of measurement
Complete blood count

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: granulocyte colony stimulating factor three times prior to chemotherapy and one time after the chemotherapy

Category
Treatment - Drugs

2

Description
Control group: placebo, three times prior to chemotherapy and one time after the chemotherapy

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Tabriz Children's Hospital

Full name of responsible person
Dr. Mir Hamid Rabbani Shabestary

Street address
Tabriz Children's Hospital, Sheshgelan street, Tabriz, Iran

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
Dr.Seyyed Kazem Shakouri

Street address

Vice chancellor for reserach, Central building of Tabriz University of Medical Sciences, Daneshgah street, Golgasht street, Tabriz, Iran

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
Tabriz Children's hospital

Full name of responsible person
Dr.Mir Hamid Rabbani Shabestary

Position
Resident of Children's diseases

Other areas of specialty/work

Street address
Tabriz Children's hospital, Sheshgelan street, Tabriz, Iran

City
Tabriz

Postal code
5163817861

Phone
+98 41 3526 2277

Fax
+98 41 3526 2278

Email
rabbanihamid@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz Children's hospital

Full name of responsible person
Dr.Azim Rezamand

Position
Pediatrc Hematologist and oncologist, Assistant Professor

Other areas of specialty/work

Street address
Hematology and Oncology ward, Tabriz Children's hospital, Sheshgelan street, Tabriz, Iran

City
Tabriz

Postal code

Phone
+98 41 3334 2299

Fax
+98 41 3526 2280

Email
rezamand@tbzmed.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Tabriz Children's hospital

Full name of responsible person
Dr.Mir Hamid Rabbani Shabestary

Position
Resident of Children's diseases

Other areas of specialty/work

Street address
Tabriz Children's hospital, Sheshgelan street, Tabriz, Iran

City
Tabriz

Postal code
5163817861

Phone
+98 41 3526 2277

Fax

Email
hamidrabbani@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