

# 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

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##### Email address

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##### 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 neuroblastoma

**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

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**Full name of responsible person**

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**Position**

Pediatrc Hematologist and oncologist, Assistant Professor

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**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

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**Full name of responsible person**

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**Position**

Resident of Children's diseases

**Other areas of specialty/work****Street address**

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**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*