

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Oct 2026

The effectiveness of a single dose of peg-filgrastim (PD-Lasta) compared with Filgrastim (PD-grastim) to increase the absolute number of neutrophils (ANC) in patients with AML after chemotherapy

Protocol summary

Study aim

comparing the effect of peg-filgrastim (PD-Lasta) with filgrastim (PD-grastim) in increasing neutrophils in AML patients after chemotherapy.

Design

58 patients with AML after one or two courses of induction chemotherapy (cytarabine + daunorubicin) and after achieving remission, undergoes consolidation with high-dose cytarabine (4 courses). Patients are divided into two groups via Haphazard number table. The first group 24 hours after consolidation chemotherapy receive daily subcutaneous PD-grastim 5 µgr/kg dose and the second group 24 hours after consolidation chemotherapy receive a PD-Lasta 6mg dose. Then daily ANC (absolute neutrophil count) of the patients in two groups are recorded until reaching above 1500 per microlitre.

Settings and conduct

The Data were collected by taking a daily questionnaire and a daily CBC test and measuring the absolute neutrophil count for each patient in case of neutropenia ($ANC \leq 1.5 \times 10^9/L$).

Participants/Inclusion and exclusion criteria

All patients between 15 to 65 years old with AML who are in remission following induction chemotherapy after receiving high-dose cytarabine enter the trial and if any patient is suffering from sepsis is removed from the trial.

Intervention groups

The first group 24 hours after consolidation chemotherapy receive daily subcutaneous PD-grastim 5 µgr/kg dose and the second group 24 hours after consolidation chemotherapy receive a PD-Lasta 6mg dose.

Main outcome variables

Main outcome measures: The primary outcome: The effect of PD-Lasta usage in increasing patients ANC above 1500/ul. Secondary outcomes: The effect of PD-Lasta usage in reducing the incidence of infection after

chemotherapy.

General information

Reason for update

To Submit the Final Report

Acronym

none

IRCT registration information

IRCT registration number: **IRCT2015072623349N1**

Registration date: **2016-01-19, 1394/10/29**

Registration timing: **registered_while_recruiting**

Last update: **2022-06-27, 1401/04/06**

Update count: **1**

Registration date

2016-01-19, 1394/10/29

Registrant information

Name

Mohsen Esfandbod

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 982 181 631

Email address

sfandbod@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Pooyesh Darou Biopharmaceutical Company

Expected recruitment start date

2015-07-23, 1394/05/01

Expected recruitment end date

2016-07-22, 1395/05/01

Actual recruitment start date

2015-07-29, 1394/05/07

Actual recruitment end date

2016-02-09, 1394/11/20

Trial completion date

2017-07-11, 1396/04/20

Scientific title

The effectiveness of a single dose of peg-filgrastim (PD-Lasta) compared with Filgrastim (PD-grastim) to increase the absolute number of neutrophils (ANC) in patients with AML after chemotherapy

Public title

The effect of long-acting subcutaneous drug in increasing white blood cells in patients with leukemia after chemotherapy

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Denovo AML Age 15-65 Achieved complete remission after induction chemotherapy Received high dose of Cytarabine in consolidation chemotherapy

Exclusion criteria:

Secondary AML ECOG performance status ≥ 3 Have any effective disease (such as cardiovascular disease, renal disease, liver disease, pulmonary disease, diabetes, high blood pressure etc.) or receiving drugs and continuous treatment

AgeFrom **15 years** old to **65 years** old**Gender**

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample sizeTarget sample size: **58**Actual sample size reached: **60****Randomization (investigator's opinion)**

Randomized

Randomization description

with 6 patients block randomized to two classes of the drugs

Blinding (investigator's opinion)

Single blinded

Blinding description

AML patients were blindly allocated to short acting and long acting group receiving short acting and long acting G-CSF respectively

Placebo

Not used

Assignment

Parallel

Other design features

Haphazard number table

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tehran University of Medical Sciences

Street address

Keshavarz Boulevard, Cornre of the Ghods Street

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2015-08-03, 1394/05/12

Ethics committee reference number

27325

Health conditions studied**1****Description of health condition studied**

Acute Meyeloid Lukemia

ICD-10 code

C81-C96 -

ICD-10 code description

C81-C96 Malignant neoplasms, stated or presumed to be primary, of lymphoid, haematopoietic and related tissue - C92.0Acute myeloblastic leukaemia [AML]

Primary outcomes**1****Description**

The time of reaching ANC above 1500/ul by using PD-lasta

Timepoint

Patient daily absolute neutrophil count (ANC) record until ANC reaches above 1500 per microlitre

Method of measurement

Colter

Secondary outcomes**1****Description**

The effect of PD-Lasta in reducing the incidence of infection after chemotherapy

Timepoint

From day 14 after chemotherapy

Method of measurement

Clinical evaluation

Intervention groups

1

Description

Intervention group patients after receiving one or two courses of induction chemotherapy (cytarabine+daunorubicin) and after achieving complete remission, are treated with high dose ara-c (2 to 4 cycle). After 24 hour of chemotherapy, patients receive a single long-acting subcutaneous GCSF (PD-lasta).

Category

Treatment - Drugs

2

Description

Control group patients after receiving one or two courses of induction chemotherapy (cytarabine+daunorubicin) and after achieving complete remission, are treated with high dose ara-c (2 to 4 cycle). After 24 hour of chemotherapy patients receive daily short-acting GCSF (PD-filgrastim).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hematology Oncology ward of Valiasr Hospital,
Imama Khomeini Hospital Complex

Full name of responsible person

Dr Mohsen Esfandbod

Street address

Valiasr Hospital of Imam Khomeini hospital complex,
Gharib Street, End of the Keshavarz Boulevard

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 6658 1593

Email

sfandbod@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Pooyesh Darou Biopharmaceutical Company

Full name of responsible person

Shima Tanha

Street address

No.13, 5th Ave, Fatemi St, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1415763863

Phone

+98 21 8897 0979

Email

info@pooyeshdarou.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Pooyesh Darou Biopharmaceutical Company

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Mohsen Esfandbod

Position

Adult clinical Hematology Oncology/ Assistant
Professor

Latest degree

Subspecialist

Other areas of specialty/work

adult clinical hematologist oncologist

Street address

Keshavarz Boulevard, Cornre of the Ghods Street

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 81631

Fax

+98 21 8898 9664

Email

sfandbod@sina.tums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Dr Gholamreza Toogeh

Position
Adult clinical Hematology Oncology/ Associate Professor

Latest degree
Subspecialist

Other areas of specialty/work
adult clinical hematologist oncologist

Street address
Keshavarz Boulevard, Cornre of the Ghods Street

City
Tehran

Province
Tehran

Postal code
1417653761

Phone
+98 21 81631

Fax
+98 21 8898 9664

Email
gh_toogeh@yahoo.com

Web page address

Province
Tehran

Postal code
1417653761

Phone
+98 21 81631

Fax
+98 21 8898 9664

Email
fariba_zarrabi@yahoo.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
comparison of long acting and short acting G-CSF in neutrophil recovery in AML patients after consolidation

When the data will become available and for how long
NON

To whom data/document is available
NON

Under which criteria data/document could be used
NON

From where data/document is obtainable
NON

What processes are involved for a request to access data/document
NON

Comments
No special comment

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Fariba Zarrabi

Position
Research Administrate at Thrombosis Hemostasis Research Center/ MSc in Genetics

Latest degree
Master

Other areas of specialty/work
Medical Genetics

Street address
Keshavarz Boulevard, Cornre of the Ghods Street

City
Tehran

Trial results

Please tick if results have been published
Yes

Summary result posting date
2022-06-27, 1401/04/06

Table of baseline comparison

Characteristic	PD-Grastim(n=22)	PD-Lasta(n=29)
Age, years		
Mean (SD)	46.5 (14.1)	42.3 (13.3)
Range	15-65	15-65
Sex, n (%)		
Male	10 (41.4)	24 (82.8)

Female	12 (58.6)	5 (17.2)
*Cytogenetic, n		
Intermediate	14	24
Favorable	3	4
Unfavorable	1	-

*Cytogenetic data were not available in five patients.

Participant flow diagram

Inclusion criteria	Exclusion criteria
Age 15-65	Secondary AML
Denovo AML	ECOG performance status $\geq$ 3
Achieved complete remission after induction chemotherapy	Have any effective disease (such as cardiovascular disease, renal disease, liver disease, pulmonary disease, diabetes, high blood pressure etc.) or receiving drugs and continuous treatment
Received high dose of Cytarabine in consolidation chemotherapy	

Table of variable outcomes' results

Table of adverse events

Complication	PD-Grastim(n=22)	PD-Lasta(n=29)
Fever, n (%)	3 (13.6%)	3 (10.3%)
Bone pain, n (%)	13 (59.1%)	12 (41.4%)
Fatigue, n (%)	1 (3.4%)	1 (3.4%)
Headache, n (%)	1 (3.4%)	1 (3.4%)

First publication date

2021-04-01, 1400/01/12

Abstract of published paper

The median time to recovery of neutrophils was 11.00 and 13.00 days for short-acting G-CSF (PD-Grastim) (n=22) and long-acting G-CSF (PD-Lasta) (n=29) groups, respectively (U=186.5, P>0.05 two-tailed). The incidence of adverse effects was similar in both short-acting G-CSF (PD-Grastim) and long-acting G-CSF (PD-Lasta) groups.