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≤1.5×109/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

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Mohsen Esfandbod

Name of organization / entity
Tehran University of Medical Sciences

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Iran (Islamic Republic of)

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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
Age
From **15 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target 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 respetively
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
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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Pooyesh Darou Biopharmaceutical Company
Full name of responsible person
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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
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Position
Adult clinical Hematology Oncology/ Assistant Professor
Latest degree
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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

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≥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.