

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

A Pilot Study of Sorafenib (Soranex)[®] (FLT3 Inhibitor) Administration as Maintenance Therapy Following Allogeneic Transplant for AML Patients with FLT3/ITD mutation

Protocol summary

Study aim

Improved relapse-free survival (RFS) for patients with FLT3/ITD AML with Maintenance therapy by a potent FLT3 inhibitor after allogeneic transplant

Design

A concealed, randomized phase 3, triple blinded, controlled clinical trial with a parallel group design of 52 patients

Settings and conduct

Patients who have inclusion criteria that have admitted in HSCT wards of Shariati hospital will received oral Sorafenib (Soranex)[®] (200 mg 2 times per day) or placebo from engraftment for a 3 months period, without relapse or intolerance adverse effect.

Participants/Inclusion and exclusion criteria

Subjects with AML with the FLT3-ITD mutation who have undergone allogeneic HSCT peripheral blood able to swallow whole pills evidence of relapsed/recurrent/residual disease as assessed by bone marrow aspirate and biopsy performed between days 30-60 any other hemorrhage/bleeding or dermal complication related to intervention CTCAE v. 4.0 > = grade 3 within 4 weeks of starting study drug

Intervention groups

Intervention group: Subjects will be taken Sorafenib (Soranex)[®] 400 mg per day orally beginning after the time of engraftment for a 3 months period. Sorafenib (Soranex)[®] tablets (200 mg) provided by Noavaran Droui Kimia Co. Control group: patients scheduled to receive allogeneic HSCT consecutively screened for inclusion in the study and will received placebo BID orally beginning after the time of engraftment for a 3 months period.

Main outcome variables

Disease-free survival (DFS)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140818018842N21**

Registration date: **2021-12-26, 1400/10/05**

Registration timing: **registered_while_recruiting**

Last update: **2021-12-26, 1400/10/05**

Update count: **0**

Registration date

2021-12-26, 1400/10/05

Registrant information

Name

Leyla Sharifi Aliabadi

Name of organization / entity

Research Institute for Hematology, Oncology and Stem Cell Transplantation, Tehran University of Medic

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-19, 1399/12/01

Expected recruitment end date

2024-03-19, 1402/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Pilot Study of Sorafenib (Soranex)[®] (FLT3 Inhibitor) Administration as Maintenance Therapy Following Allogeneic Transplant for AML Patients with FLT3/ITD mutation

Public title

Sorafenib (Soranex)[®] for prevention of relapse in AML Patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Subjects with AML with the FLT3-ITD mutation who have undergone allogeneic HSCT Peripheral blood chimerism studies showing $\geq 90\%$ of all cells are of donor origin ECOG performance status 0-2 Able to swallow whole pills Adequate hematologic and hepatic function

Exclusion criteria:

Evidence of relapsed/recurrent/residual disease as assessed by bone marrow aspirate and biopsy performed between days 30-60 after HSCT Active acute graft vs host disease requiring an equivalent dose of > 0.5 mg/kg/day of prednisone Ongoing uncontrolled infection Cardiac ventricular arrhythmias requiring anti-arrhythmic therapy Known HIV infection or chronic hepatitis B or C Any other hemorrhage/bleeding or dermal complication related to intervention CTCAE v. 4.0 $\geq$ Grade 3 within 4 weeks of starting study drug Receiving any other investigational agents

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

This is a randomized controlled clinical trial with parallel design. participants randomly allocated to one of two groups according to balanced block randomization method. Group A is considered as the (intervention) that will receive Sorafenib (Soranex)[®] (FLT3 Inhibitor) and group B is considered as the control that will receive placebo. In order to concealment of the balanced block randomization method, the drug and placebo are made in the same package by the pharmaceutical company and will be provided to a member of the study team who will encode them in a sequence of numbers according to

the balanced block randomization list. patients who meet all eligibility criteria will receive the coded drug. Except for the above person, all members of the research team and participants were blinded to the allocation list.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Sorafenib (Soranex)[®] and placebo are made in the form of similar tablets by the pharmaceutical company. Only one person on the study team who is responsible for randomization takes the tables, puts them in similar packages and encodes as a sequence of numbers according to a list of Balanced Block Randomization. Upon arrival of the each eligible patient, the coded package will be provided with a label that includes the drug numerical code, patient name, and study code. Except for the above person, no body, including the treating physician, the person in charge of data collection and analysis, statistical analyzer, and the patient himself, are aware of the type of drug. Allocation concealment samples are done by the people of the center that they and patients do not have any information about the researcher's aim.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethic committee of Hematology- Oncology and Stem Cell Transplantation Research Center, Tehran Univer

Street address

Kargar shomali Ave., Shariati hospital

City

Tehran

Province

Tehran

Postal code

1411713135

Approval date

2020-07-01, 1399/04/11

Ethics committee reference number

IR.TUMS.HORCSCT.REC.1399.012

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

Acute myeloblastic leukemia

ICD-10 code

C92.0

ICD-10 code description

Acute myeloblastic leukemia

Primary outcomes

1

Description

Cumulative incidence Relaps

Timepoint

1 year

Method of measurement

Patient follow up for absent of relapse by Bone Marrow aspiration and biopsy, Physical exam and lab test

2

Description

One year relapse free survival (RFS)

Timepoint

1 year

Method of measurement

Patient follow up for absent of relapse by Bone Marrow aspiration and biopsy, Physical exam and lab test

Secondary outcomes

1

Description

One year overall survival (OS)

Timepoint

1 year

Method of measurement

Follow up visit

2

Description

Cumulative incidence acute GvHD

Timepoint

After 100 daye post HSCT

Method of measurement

Physical exam and lab test

Intervention groups

1

Description

Intervention group:Subjects will be taken Sorafenib (Soranex)[®] 400 mg per day orally beginning after the time of engraftment for a 3 months period. Sorafenib (Soranex)[®] tablets (200 mg) provided by Noavaran Droui Kimia Co.

Category

Treatment - Drugs

2

Description

Control group: patients scheduled to receive allogenic

HSCT consecutively screened for inclusion in the study and will received placebo BID orally beginning after the time of engraftment for a 3 months period.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Hematology- Oncology and Stem Cell Transplantation Research Center, Tehran University of Medical Sci

Full name of responsible person

Maryam Barkhordar

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Shariati hospital, Kargar shomali Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Seied Asadollah Mousavi

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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

Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

2

Sponsor

Name of organization / entity

Noavaran Daroui Kimia

Full name of responsible person

Esmail Moazeni

Street address

Unit 4, No.8, Hamedan St., North Kargar St., Tehran.
Iran.

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info@kimia-pharma.co

Web page address

<http://www.kimia-pharma.co/en/contact-us/>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Noavaran Daroui Kimia

Proportion provided by this source

50

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

Industry

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Maryam Barkhordar

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Hematology
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Maryam Barkhordar

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Leyla Sharifi Aliabadi

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Master

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available