Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Investigating the effect of intranasal corticosteroids on the incidence of invasive fungal sinusitis in patients receiving stem cell transplantation: A randomized clinical trial study

Protocol summary

Study aim
effect of intranasal corticosteroids on invasive fungal sinusitis in bone marrow transplant

Design
A controlled, double-blind, randomized, phase 3 clinical trial with parallel groups on 426 patients. The rand function of Excel software was used for randomization

Settings and conduct
patient who received bone marrow transplant referred with acute rhinosinusitis to Taleghani hospital of Tehran were randomly divided in two groups with block randomization method to intervention and control group. This research is a double blind study that patients and physician and data analyzers are blinded to study intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: patients who were at least 18 years old. Recipients of allogeneic or autologous hematopoietic stem cell transplant in the past 3 months; exclusion criteria: evidence of active fungal sinusitis or previous fungal sinusitis, Patients taking systemic antifungal medications, History of facial trauma, History of previous sinus and nose surgery, Patients diagnosed with chronic rhinosinusitis with or without nasal polyposis

Intervention groups
Patients in the intervention group receive fluticasone propionate nasal spray producted by kooshan pharmed company at a daily dose of 200 micrograms, and patients in the control group receive a placebo nasal spray that is similar in appearance to fluticasone spray. The spray is inhaled twice a day, one puff each time, equivalent to 100 micrograms, in each nostril for 8 weeks. The spray is shaken before use and the tip of the spray is kept away from the nasal septum.

Main outcome variables
incidence of invasive fungal sinusitis

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200926048841N4**
Registration date: **2026-06-12, 1405/03/22**
Registration timing: **registered_while_recruiting**

Last update: **2026-06-12, 1405/03/22**
Update count: **0**

Registration date
2026-06-12, 1405/03/22

Registrant information

Name
mahboobe asadi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 2640 5257

Email address
ma_asadi@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-03-07, 1404/12/16

Expected recruitment end date
2026-07-07, 1405/04/16

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of intranasal corticosteroids on the incidence of invasive fungal sinusitis in patients receiving stem cell transplantation: A randomized clinical trial study

Public title
The effect of intranasal corticosteroids on the incidence of invasive fungal sinusitis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients who were at least 18 years old at the time of the study Recipients of allogeneic or autologous hematopoietic stem cell transplant in the past 3 months A persistent absolute neutrophil count of less than 1000 cells per cubic millimeter for a minimum continuous period of seven days, documented by at least two consecutive laboratory measurements

Exclusion criteria:
Patients who had evidence of active fungal sinusitis or previous fungal sinusitis based on clinical, radiological, or microbiological criteria, Patients taking systemic antifungal medications, including prophylactic or curative therapy History of facial trauma that required surgical intervention History of previous sinus and nose surgery Congenital anomalies of the skull and face. Patients diagnosed with chronic rhinosinusitis with or without nasal polyposis Patients with known hypersensitivity to fluticasone propionate or any component of the nasal spray formulation.

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **426**

Randomization (investigator's opinion)
Randomized

Randomization description
Block randomization method. Given the block size of 2, there are two ways to assign participants to a block: AB or BA. (A) stands for fluticasone propionate spray; (B) stands for placebo spray. Using Microsoft Excel software we produce 213 numbers. For even numbers AB combination and for odd numbers BA combination are chosen.

Blinding (investigator's opinion)
Double blinded

Blinding description
fluticasone propionate spray and placebo spray are identical in shape and package.Patients were blinded to which group they entered,but they were told that they could use nasal spray fluticasone propionate or placebo spray.The researcher and the author of the article are blinded to which group A or B belong to intervention group. The evaluations after the operation were performed by a person who was blinded to the patient group.The statistical analyzer was also blinded to the groups.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shahid Beheshti University of medical sciences

Street address
Shahid Beheshti university of medical science, Erabi Ave, Velenjak ,

City
Tehran

Province
Tehran

Postal code
1916665354

Approval date
2026-02-08, 1404/11/19

Ethics committee reference number
IR.SBMU.RETECH.REC.1404.1085

Health conditions studied

1

Description of health condition studied
Stem cells transplant patient

ICD-10 code
Z94.84

ICD-10 code description
Stem cells transplant status

2

Description of health condition studied
Acute myeloblastic leukemia

ICD-10 code
C92.0

ICD-10 code description
Acute myeloblastic leukemia

3

Description of health condition studied
Acute myeloid leukemia with multilineage dysplasia
ICD-10 code
C92.A
ICD-10 code description
Acute myeloid leukemia with multilineage dysplasia

Primary outcomes

1

Description
Incidence of invasive fungal sinusitis
Timepoint
before intervention and 2 months after intervention
Method of measurement
mucosal biopsy and pathology assessment

Secondary outcomes

1

Description
total mortality rate
Timepoint
2 months after intervention
Method of measurement
checking patients' record

2

Description
mortality rate because of invasive fungal sinusitis
Timepoint
2 months after intervention
Method of measurement
mucusal biopsy and checking patients' record

3

Description
duration of hospitalization
Timepoint
2 months after intervention
Method of measurement
checking patients' record

4

Description
duration of hospitalization in ICU
Timepoint
2 months after intervention
Method of measurement
checking patients' record

5

Description
duration of neutropenic status
Timepoint
Before intervention and 2 months after intervention
Method of measurement
Lab tests and patients' record

6

Description
endoscopic sinus surgery rate
Timepoint
2 months after intervention
Method of measurement
checking patients' record

Intervention groups

1

Description
Intervention group: Patients who receive kooshan pharmed Company's fluticasone propionate nasal spray at a daily dose of 200 micrograms (100 micrograms in each nostril, twice a day) for 8 weeks. The doctor instructs patients to shake the spray before use and to keep the tip of the spray away from the nasal septum when using it inside the nose.
Category
Treatment - Drugs

2

Description
Control group: They receive a placebo nasal spray producted by koosha pharmed company containing a rinse serum that is similar in appearance to fluticasone propionate spray (one puff in each nostril twice a day) for 8 weeks. The doctor instructs patients to shake the spray before use and to keep the tip of the spray away from the nasal septum when using it inside the nose.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Taleghani Hospital
Full name of responsible person
Mahboobe Asadi
Street address
Taleghani Hospital,Erabi Ave,Velenjak
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address
Shahid Beheshti University of Medical Sciences, , Vice Chancellor for Research and Technology,Erabi Ave,Velenjak
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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
Shahid Beheshti University of Medical Sciences

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
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mahboobe Asadi
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
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Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

participant data sets are to be shared

When the data will become available and for how long

These data files will become available one year after publication

To whom data/document is available

The data is only available for people working in academic institutions

Under which criteria data/document could be used

The data is only available for people working in academic institutions

From where data/document is obtainable

The data is obtainable from the corresponder author via email

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

The data is obtainable from the corresponder author via email

Comments