

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Aug 2026

### Comparative study of the therapeutic results of Carboplatin, Etoposide, ARAC, Melfalan chemotherapy regimes with CCNU, Etoposide, ARAC, Melfalan diet as a diet before autologous stem cell transplantation in patients with resistant / recurrent lymphoma

#### Protocol summary

##### Study aim

Determining and comparing the therapeutic results of different chemotherapy regimens before autologous stem cell transplantation in patients with resistant/relapsed lymphoma.

##### Design

Clinical trial, with parallel groups, without blinding, non-randomized, phase 2 on 44 patients.

##### Settings and conduct

In this non-blinded, non-randomized clinical trial study, 44 patients with resistant/relapsed lymphoma, referring to Omid Hospital in Isfahan, were enrolled in 2 groups. In two groups, heavy conditioning will be done under two chemotherapy regimens. Then patients undergo autologous stem cell transplantation. After Engraft, the patient is discharged. Then the transplant complications and the possibility of disease recurrence will be evaluated in two ways.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: being over 18 years old, having Hodgkin's/Non-Hodgkin's lymphoma resistant/relapsed and consenting to participate in the study. Exclusion criteria include patients who do not have suitable stem cells for transplantation during the initial stages of stem cell transplantation.

##### Intervention groups

First intervention group: First, the patient undergoes mobilization. Then the stem cells are separated from the peripheral blood. At this stage, the patient is treated with heavy conditioning chemotherapy including Etoposide, ARAC, Melphalan and Carboplatin. Second intervention group: First, the patient undergoes mobilization. Then the stem cells are separated from the peripheral blood. At this stage, the patient is treated with heavy conditioning chemotherapy including Etoposide, ARAC, Melphalan and CCNU.

#### Main outcome variables

Transplant complications, disease recurrence

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200825048515N70**

Registration date: **2023-09-06, 1402/06/15**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-09-06, 1402/06/15**

Update count: **0**

##### Registration date

2023-09-06, 1402/06/15

##### Registrant information

##### Name

Asieh Maghami Mehr

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 0000 0000

##### Email address

asimaghami@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-07-21, 1402/04/30

##### Expected recruitment end date

2024-03-20, 1403/01/01

##### Actual recruitment start date

empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty  
**Scientific title**  
Comparative study of the therapeutic results of Carboplatin, Etoposide, ARAC, Melfalan chemotherapy regimes with CCNU, Etoposide, ARAC, Melfalan diet as a diet before autologous stem cell transplantation in patients with resistant / recurrent lymphoma

**Public title**  
Comparative study of treatment results of different chemotherapy in patients with lymphoma cancer

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Age above 18 years Having Hodgkin/non-Hodgkin of lymphoma resistant/relapsed Consent to participate in the study  
**Exclusion criteria:**  
Patients who do not have suitable stem cells for transplantation during the initial stages of stem cell transplantation

**Age**  
From 18 years old

**Gender**  
Both

**Phase**  
2

**Groups that have been masked**  
No information

**Sample size**  
Target sample size: 44

**Randomization (investigator's opinion)**  
Not randomized

**Randomization description**

**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**  
**Name of ethics committee**  
Ethics committee of Isfahan University of Medical Sciences  
**Street address**

Street address Isfahan University of Medical Sciences, Hezar Jarib Ave., Azadi Sq

**City**  
Isfahan

**Province**  
Isfahan

**Postal code**  
8179964167

**Approval date**  
2020-11-24, 1399/09/04

**Ethics committee reference number**  
IR.MUI.MED.REC.1399.754

## Health conditions studied

### 1

**Description of health condition studied**  
Hodgkin lymphoma

**ICD-10 code**  
C81.9

**ICD-10 code description**  
Hodgkin lymphoma, unspecified

### 2

**Description of health condition studied**  
Non Hodgkin lymphoma

**ICD-10 code**  
C85.90

**ICD-10 code description**  
Non-Hodgkin lymphoma, unspecified, unspecified site

## Primary outcomes

### 1

**Description**  
Transplant complications

**Timepoint**  
From the time of intervention every two weeks, then every one month, and then every two months until finally one year

**Method of measurement**  
Observation

### 2

**Description**  
Survival

**Timepoint**  
Up to one year after transplantation

**Method of measurement**  
Observation

## Secondary outcomes

empty

## Intervention groups

## 1

### Description

First intervention group: First, the patient undergoes mobilization (stimulation of stem cells to move from the BM side to the peripheral blood by means of GCSF medicine). Then stem cells are separated from peripheral blood by OPTIA device with apheresis technique. At this stage, the patient is being treated with heavy conditioning chemotherapy including Etoposide 300 mg/m<sup>2</sup> (2 to 3 days), ARAC 300 mg/m<sup>2</sup> (2 to 3 days), Melphalan 140 mg/m<sup>2</sup> (1 day). and Carboplatin 750 mg/m<sup>2</sup> (2 to 3 days) is placed.

### Category

Treatment - Drugs

## 2

### Description

Second intervention group: First, the patient undergoes mobilization (stimulation of stem cells to move from the BM to the peripheral blood by means of GCSF). Then stem cells are separated from peripheral blood by OPTIA device with apheresis technique. At this stage, the patient is being treated with heavy conditioning chemotherapy including Etoposide 300 mg/m<sup>2</sup> (2 to 3 days), ARAC 300 mg/m<sup>2</sup> (2 to 3 days), Melphalan 140 mg/m<sup>2</sup> (1 day). and CCNU is placed at 200 mg/m<sup>2</sup> (4 days).

### Category

Treatment - Drugs

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Seyed Al Shahada Hospital of Isfahan

#### Full name of responsible person

Alireza Sadeghi

#### Street address

Seyed Al Shahada Hospital, Farshadi River Alley, Khayyam Street

#### City

Isfahan

#### Province

Isfahan

#### Postal code

8174675731

#### Phone

+98 31 3235 0218

#### Email

sadeghi\_hem@yahoo.com

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Esfahan University of Medical Sciences

#### Full name of responsible person

Gholamreza Askari

#### Street address

Vice Chancellor for Research, School of Medicine, Hezar Jarib Street, Isfahan.

#### City

Isfahan

#### Province

Isfahan

#### Postal code

8174673461

#### Phone

+98 31 3668 8597

#### Email

dean@med.mui.ac.ir

#### Grant name

#### Grant code / Reference number

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

No

#### Title of funding source

Isfahan 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

## Person responsible for general inquiries

### Contact

#### Name of organization / entity

Esfahan University of Medical Sciences

#### Full name of responsible person

Alireza Sadeghi

#### Position

Assistant Professor

#### Latest degree

Subspecialist

#### Other areas of specialty/work

Hematology

#### Street address

Seyed Al Shahada Hospital, Farshadi River Alley, Khayyam Street

#### City

Isfahan

#### Province

Isfahan

#### Postal code

8174675731

#### Phone

+98 31 3235 0218

#### Fax

#### Email

sadeghi\_hem@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Alireza Sadeghi

**Position**

Assistant Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Hematology

**Street address**

Seyed Al Shahada Hospital, Farshadi River Alley,  
Khayyam Street

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174675731

**Phone**

+98 31 3235 0218

**Fax****Email**

sadeghi\_hem@yahoo.com

## Person responsible for updating data

### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Yaser Salehi najafabadi

**Position**

Non-faculty specialist doctor

**Latest degree**

Specialist

**Other areas of specialty/work**

Hematology

**Street address**

Seyed Al Shahada Hospital, Farshadi River Alley,  
Khayyam Street

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174675731

**Phone**

+98 31 3235 0218

**Fax****Email**

dr.y.salehi@gmail.com

## 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