

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 2026

### Vaccination of diffuse B cell lymphoma patients by use of tumor antigens and autologous dendritic cells complex

#### Protocol summary

Mazandaran University of Medical Sciences and Health Services

#### Summary

The Purpose of this study is to determine the effect of dendritic cells and tumor antigen complex capability in preventing tumor development. 10 lymphoma subjects will be randomly divided to two equal groups. After antigen priming, one group will receive a median of  $6.5 \times 1000000$  dendritic cells which are subcutaneously injected close to inguinal lymph nodes, twice a day. TCD4 and tumor size will be measured one week after intervention.

#### Expected recruitment start date

2009-06-22, 1388/04/01

#### Expected recruitment end date

2011-11-22, 1390/09/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT138712071715N1**

Registration date: **2009-05-31, 1388/03/10**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2009-05-31, 1388/03/10

##### Registrant information

###### Name

Saeid Abedian

###### Name of organization / entity

Mazandaran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 335430810151

###### Email address

sabedian@mazums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

#### Scientific title

Vaccination of diffuse B cell lymphoma patients by use of tumor antigens and autologous dendritic cells complex

#### Public title

Vaccination of cancer patients for preventing cancer development

#### Purpose

Prevention

#### Inclusion/Exclusion criteria

Inclusion criteria: Presence of diffuse b cell lymphoma

Exclusion criteria: Presence o any other kind of cancer except for lymphoma

#### Age

From **40 years** old to **60 years** old

#### Gender

Both

#### Phase

1

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **10**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Not blinded

### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

### 1

#### Registry name

Lymphoma

#### Secondary trial Id

#### Registration date

2009-04-05, 1388/01/16

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Mazandaran University of Medical Sciences and Health Services

##### Street address

Mazandaran University of Medical Sciences, Imam square,

##### City

Sari

##### Postal code

#### Approval date

2009-03-03, 1387/12/13

#### Ethics committee reference number

116-87

## Health conditions studied

### 1

#### Description of health condition studied

Lymphoma

#### ICD-10 code

C85.1

#### ICD-10 code description

B-cell lymphoma, unspecified

## Primary outcomes

### 1

#### Description

The number of TCD4

#### Timepoint

one week after injection

#### Method of measurement

Floctometry

### 2

#### Description

The number of TCD8

#### Timepoint

one week after injection

#### Method of measurement

Floctometry

## Secondary outcomes

### 1

#### Description

Interleukin 2

#### Timepoint

7 to 14 days after injection

#### Method of measurement

eliza

### 2

#### Description

Interleukin 4

#### Timepoint

7 to 14 days after injection

#### Method of measurement

ELIZA method

### 3

#### Description

Interleukin 10

#### Timepoint

7 to 14 days after injection

#### Method of measurement

ELIZA method

### 4

#### Description

Interleukin 17

#### Timepoint

7 to 14 days after injection

#### Method of measurement

ELIZA method

## Intervention groups

### 1

#### Description

After antigen priming, subcutaneous injection of median of  $6.5 \times 1000000$  (0.5 ml) dendritic cells, close to inguinal lymph nodes, twice a day

#### Category

*empty*

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Imam Khomaini Hospital

**Full name of responsible person**

Saeid Abedian

**Street address**

Medecine collage, Mazandaran University of Medical Sciences

**City**

Sari

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Saeid Abedian

**Street address**

Medecine collage, Mazandaran University of medical Sciences

**City**

Sari

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Mazandaran University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Motahareh Kheradmand

**Position**

Master of Science on Nursing.

**Other areas of specialty/work**

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Mazandaran University of Medical Sciences

**Full name of responsible person**

Saeid Abedian

**Position**

PhD in Immunology

**Other areas of specialty/work**

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PhD in Immunology/Assistant Professor

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bedian@mazums.ac.ir

**Web page address**

**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*  
**Statistical Analysis Plan**  
*empty*  
**Informed Consent Form**  
*empty*  
**Clinical Study Report**

*empty*  
**Analytic Code**  
*empty*  
**Data Dictionary**  
*empty*