

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### A clinical trial on clinical response and complications of treatment with interferon alpha 2b in patients with basal cell carcinoma

#### Protocol summary

##### Summary

This study will assess the effect of interferon alpha 2b in treatment of basal cell carcinoma of skin. Main inclusion criteria are provision of informed consent for participation; definitive diagnosis of basal cell carcinoma of skin in pathology; and age equal or above 18 years. Main exclusion criteria are morphea-like basal cell carcinoma of skin; nodulo-ulcerative basal cell carcinoma; pregnancy and breast-feeding; history of severe complications with interferon alpha 2b; no intent to complete the treatment course; no intent to complete the follow-up period; history of cardiovascular disease; history of thromboembolic disease; local radiotherapy on the target region; history of arsenic exposure; and immune insufficiency. This is an unblinded, prospective, single-grouped, one-centered study. Twenty patients who have pathologic diagnosis of basal cell carcinoma and who are not candidate for surgical excision of the lesion will be enrolled. The treatment involves subcutaneous administration of three million unite interferon alpha 2b ampule at a dose of 0.15 cubic centimeters per lesion three times a week for three successive weeks. Lesion changes will be assessed with camera pictures. The patients will be examined for clinical response and complications of treatment and will be followed up after completion of treatment up to one year. In case of consent, a second biopsy for assessment of pathologic response will be performed using 3 millimeter punch and will be analyzed in the laboratory.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017093017756N30**

Registration date: **2017-10-01, 1396/07/09**

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

Last update:

Update count: **0**

##### Registration date

2017-10-01, 1396/07/09

##### Registrant information

###### Name

Mohammad Bagher Roozgar

###### Name of organization / entity

Birjand University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 56 3239 5680

###### Email address

mbroozgar@bums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice-chancellery for Research, Mashhad University of Medical Sciences

##### Expected recruitment start date

2017-03-21, 1396/01/01

##### Expected recruitment end date

2019-03-21, 1398/01/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

A clinical trial on clinical response and complications of treatment with interferon alpha 2b in patients with basal cell carcinoma

##### Public title

The effect of interferon alpha 2b on the treatment of basal cells cancer

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: Informed written consent for participation; definitive diagnosis of basal cell carcinoma of skin in pathology; and age 18 years old or above.

Exclusion criteria: Morphea-like basal cell carcinoma of skin; nodulo-ulcerative basal cell carcinoma; pregnancy and breast-feeding; previous history of severe complications with interferon alpha 2b; no intent to complete the treatment course; no intent to complete the follow-up period; previous history of cardiovascular disease; previous history of thromboembolic disease; local radiotherapy on the target region; previous history of arsenic exposure; and immune insufficiency.

## Age

From **18 years** old to **80 years** old

## Gender

Both

## Phase

2

## Groups that have been masked

*No information*

## Sample size

Target sample size: **20**

## Randomization (investigator's opinion)

N/A

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Single

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

##### Street address

Vice-chancellery for Research, Mashhad University of Medical Sciences, Daneshgah Ave.,

##### City

Mashhad

##### Postal code

#### Approval date

2017-01-04, 1395/10/15

#### Ethics committee reference number

IR.MUMS.fm.REC.1395.492

## Health conditions studied

### 1

#### Description of health condition studied

basal cell carcinoma

#### ICD-10 code

C44.9

#### ICD-10 code description

Malignant neoplasm of skin, unspecified

## Primary outcomes

### 1

#### Description

Clinical response

#### Timepoint

Every two months

#### Method of measurement

Physical examination

## Secondary outcomes

### 1

#### Description

Neutropenia

#### Timepoint

on a weekly basis

#### Method of measurement

Complete blood count

### 2

#### Description

Headache

#### Timepoint

on a weekly basis

#### Method of measurement

Medical history

### 3

#### Description

Fatigue

#### Timepoint

on a weekly basis

#### Method of measurement

Medical history

### 4

#### Description

Pathologic response

#### Timepoint

Two months after completion of treatment

#### Method of measurement

Biopsy

**5**

**Description**

Fever

**Timepoint**

on a weekly basis

**Method of measurement**

Physical examination

**Intervention groups**

**1**

**Description**

The treatment involves subcutaneous administration of three million unite interferon alpha 2b ampule at a dose of 0.15 cubic centimeters per lesion three times a week for three successive weeks.

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Dermatology Clinic of Imam Reza Hospital

**Full name of responsible person**

Dr Masoud Maleki

**Street address**

Imam Reza Hospital, Daneshgah Ave.,

**City**

Mashhad,

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Vice-chancellery for Research and Technology,  
Mashhad University of Medical Sciences

**Full name of responsible person**

Dr Mohsen Tafaghodi

**Street address**

Vice-chancellery of Research and Technology,  
Mashhad University of Medical Sciences, Daneshgah  
Ave.,

**City**

Mashhad

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Vice-chancellery for Research and Technology, Mashhad  
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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr. Mehdi Razmara Farzaghi

**Position**

Doctor of Medicine

**Other areas of specialty/work**

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Leishmaniasis Research Center, Ghaem Hospital,  
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Imam Reza Hospital

**Full name of responsible person**

Dr Masoud Maleki

**Position**

Dermatologist

**Other areas of specialty/work**

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**Full name of responsible person**

Mohammad Bagher Roozgar

**Position**

PhD Candidate in Translation Studies

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hadirooz@gmail.com

**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*