Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 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

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Name of organization / entity

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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 Reasearch, 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 Medicla Sciences
Full name of responsible person
Dr Mohsen Tafaghodi
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Vice-chancellery of Reasearch and Technology, Mashhad University of Medical Sciences, Daneshgah Ave.,
City
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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
Vice-chancellery for Research and Technology, Mashhad University of Medicla 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
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Doctor of Medicine
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Person responsible for scientific inquiries

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Person responsible for updating data

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Position
PhD Candidate in Translation Studies
Other areas of specialty/work
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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