

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Efficacy of Personalized Irradiation with Rhenium/Yttrium-Skin Cancer Therapy (SCT) for the Treatment of Non-Melanoma Skin Cancer

Protocol summary

Study aim

To evaluate the efficacy of personalized irradiation with Rhenium /Yttrium-Skin Cancer Therapy (SCT)

Design

This is an interventional clinical trial with a single group design of 20 patients, performed between July 2023 and March 2025 that will be followed after the treatment session.

Settings and conduct

Patients are selected and justified in the nuclear medicine center of the Persian Gulf Hospital at Bushehr. The consent form is obtained and the one-session treatment will be performed with Rhenium /Yttrium radioactive skin patch. The lesion needed to be outlined with a demographic pen using accurate visual examination, including a safety margin of approximately 5mm around it.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age ≥ 18 years, Stage I or II BCC or SCC, Confirmed Histology (with the depth of lesion noted), Subjects able and willing to comply with the requirements of the study. Exclusion criteria: inability to personally provide written informed consent or to understand and collaborate throughout the study, Inability or unwillingness to comply with study requirements, Prior treatment with surgery or radiation therapy for their target lesion(s), Malignant melanoma systemic therapy ongoing, pregnancy and/or Lactation.

Intervention groups

We are going to use a specially designed radioactive skin patch to evaluate the efficacy of personalized irradiation with Rhenium /Yttrium-Skin Cancer Therapy in the treatment of Stage I or II Basal or Squamous cell carcinoma.

Main outcome variables

Complete remission of skin cancer lesions. The technique proposed by radioactive skin patch offers the ability to treat almost every anatomical location, as well as the possibility to treat several lesions at once, leading to a

great advantage if compared with conventional treatments.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210612051548N6**

Registration date: **2023-05-24, 1402/03/03**

Registration timing: **prospective**

Last update: **2023-05-24, 1402/03/03**

Update count: **0**

Registration date

2023-05-24, 1402/03/03

Registrant information

Name

Majid Assadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 77 3332 0361

Email address

assadipoya@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-06, 1402/04/15

Expected recruitment end date

2025-03-19, 1403/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of Personalized Irradiation with Rhenium/Yttrium-Skin Cancer Therapy (SCT) for the Treatment of Non-Melanoma Skin Cancer

Public title

Rhenium/Yttrium-Skin Cancer Therapy for the Treatment of Non-Melanoma Skin Cancer

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age ≥ 18 years Stage I or II BCC (Basal Cell Carcinoma) or SCC (Squamous Cell Carcinoma) Confirmed Histology (with depth of lesion noted) Subjects with up to 3 lesions suitable to enter the study (subjects with more than 3 lesions are not excluded from the study, however 3 target lesions are determined for study evaluation only.) Subjects able and willing to comply with the requirements of the study Lesions with a depth up to 3mm confirmed on biopsy report AND deemed appropriate clinically by treating clinician Subjects who are not deemed suitable for surgery, for example due to tumour location, performance status or other comorbidities as deemed relevant by the treating clinician Patients who may have declined Surgery and/or fractionated Radiation Therapy

Exclusion criteria:

Inability to personally provide written informed consent or to understand and collaborate throughout the study Inability or unwillingness to comply with study requirements Prior treatment with surgery or radiation therapy for their target lesion(s) Depth of lesion greater than 3mm as defined by Biopsy and/or clinical assessment Lupus and Scleroderma Prior laser at the tumour site Malignant melanoma systemic therapy ongoing Any ongoing treatment for malignancy, or in the last 4 weeks prior to study entry A tumour affecting nerves or bony structures pregnancy's and/or Lactation Anatomical exclusions: NMSC's of the Medial canthus, eyelid margin (upper and lower), Vermillion lip

Age

From **18 years** old

Gender

Both

Phase

N/A

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**

Research Ethics Committees of Bushehr province university of medical sciences

Street address

Bushehr University of Medical Science, Moallem Street, Bushehr, Iran

City

Bushehr

Province

Boushehr

Postal code

45654775

Approval date

2023-02-06, 1401/11/17

Ethics committee reference number

IR.BPUMS.REC.1401.210

Health conditions studied**1****Description of health condition studied**

Non-melanoma Skin Cancer

ICD-10 code

C44

ICD-10 code description

Other and unspecified malignant neoplasm of skin

Primary outcomes**1****Description**

the longest diameter of the lesion

Timepoint

6 months

Method of measurement

Visual RECIST (Response Evaluation Criteria in Solid Tumours) tool

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Patients 18 years and older with stage I or II BCC (Basal Cell Carcinoma) or SCC (Squamous cell carcinoma)

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Nuclear Medicine Center, Khalig-e-Fars Hospital

Full name of responsible person

Majid Assadi

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Khalig-e-Fars Hospital, Taleghani Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Boushehr University of Medical Sciences

Full name of responsible person

Akram Farhadi

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Vice-Chancellor for Research and Technology of Bushehr University of Medical Sciences, Salman-e-Farsi Blvd, Bushehr, Iran.

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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

Boushehr 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

Boushehr University of Medical Sciences

Full name of responsible person

Majid Assadi

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Nuclear Medicine

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

Not applicable

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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