

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Evaluation of the therapeutic efficacy of injectable 5FU solution for basal cell carcinoma in patients referred to Loghman Hakim and Shohada-e Tajrish hospitals between 2020 and 2021

Protocol summary

Study aim

Determining the percentage of people who are completely good or smaller by injecting 5FU lesions into the lesion, Determining the relationship between response rate and initial size, anatomical location, pathology type, and duration of lesion formation, Determining the relationship between response rate with age and gender

Design

Non-random sampling is a method for sampling. This means that all clients with BCC will be eligible to study. The size of the sample is determined by 50 people according to previous articles. The diagnosis of BCC will be based on histologically.

Settings and conduct

Demographic information is recorded through a questionnaire. Then, 1 to 2 cc of 50mg / 5c 5FU solution will be injected in BCC lesion weekly. The injection is weekly and lasts until the lesion heals or lasts a maximum of 6 weeks. Then, the following criteria will be reviewed and graded at each session. The extent of the lesion reduction, the incidence of side effects, and the patient's pain and discomfort from the injection. At the end of the study, patients' lesions were removed by injection, a biopsy was performed and the pathology of the lesion was examined.

Participants/Inclusion and exclusion criteria

Inclusion criteria: people with BCC who are willing to participate in the study; people with BCC who can go for visiting weekly. Exclusion criteria: recurrent BCC; very large BCC (larger than 2 cm); BCC around the eyes; patients with lymphoma or leukemia or immunodeficient; pregnant or lactating patients.

Intervention groups

Non-random sampling is a method for sampling. This means that all clients with BCC will be eligible to study.

Main outcome variables

Size of the lesion; pathology of the lesion; duration of treatment; dose of the drug; the effectiveness of the drug; the side effects of the drug

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200205046380N2**

Registration date: **2020-09-20, 1399/06/30**

Registration timing: **registered_while_recruiting**

Last update: **2020-09-20, 1399/06/30**

Update count: **0**

Registration date

2020-09-20, 1399/06/30

Registrant information

Name

khatere zahedi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8804 5103

Email address

khaterezahedi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-04, 1399/01/16

Expected recruitment end date

2021-04-05, 1400/01/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the therapeutic efficacy of injectable 5FU solution for basal cell carcinoma in patients referred to Loghman Hakim and Shohada-e Tajrish hospitals between 2020 and 2021

Public title

Evaluation of the therapeutic efficacy of injectable 5FU solution for basal cell carcinoma in patients referred to Loghman Hakim and Shohada-e Tajrish hospitals between 2020 and 2021

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

People with BCC who are willing to participate in the study People with BCC who can go to the clinic for visiting

Exclusion criteria:

Recurrent BCC Very large BCC (larger than 2 cm) BCC around the eyes Patients with lymphoma or leukemia or immunodeficiency or in pregnant or lactating patients

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked*No information***Sample size**

Target sample size: 50

Randomization (investigator's opinion)

Randomized

Randomization description

The non-random sampling is a method for sampling. This means that all patients with BCC will be eligible to study.

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 Committee of Skin Research Center -

Shahid Beheshti University of Medical Sciences

Street address

Shohada-E-Tajrish hospital, Qods Sq., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1989934148

Approval date

2019-12-17, 1398/09/26

Ethics committee reference number

IR.SBMU.SRC.REC.1398.014

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

Basal cell carcinoma

ICD-10 code

C44.01

ICD-10 code description

Basal cell carcinoma of skin of lip

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

Assessment the complete improvement or shrinkage of the lesion

Timepoint

Weekly until the healing of lesion or up to 6 weeks

Method of measurement

Observation and questionnaire

Secondary outcomes**1****Description**

Evaluation of response to treatment based on initial size, anatomical location, pathology type, and duration of lesion formation and investigation the response to treatment based on age and gender

Timepoint

Weekly until the healing of lesion or up to 6 weeks

Method of measurement

Observation and questionnaire

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

Intervention group: 1-2 ml of the 50mg/ml 5FU solution (Kavosh Gostar Darou, Iran) will be injected in to the BCC lesion once a week until the resolution of the lesion or for a maximum duration of 6 weeks.

Category

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohadaye Tajrish Hospital

Full name of responsible person

Dr. Mohammad Mehdi Forouzanfar

Street address

Shohadaye Tajrish Hospital, Tajrish Square, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1989934148

Phone

+98 21 25719

Fax

+98 21 2271 9014

Email

pr_shohada@sbmu.ac.ir

2

Recruitment center

Name of recruitment center

Loghman Hakim Hospital

Full name of responsible person

Dr Omidvar Rezayi

Street address

Loghman Hakim Hospital, Makhsus Ave., Lashkar Crossroad, Tehran, Iran crossroad, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1333635445

Phone

+98 21 5541 9005

Email

loghman.hospital@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Gholmali Tabarsat

Street address

SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1983969411

Phone

+98 21 29901

Fax

+98 21 2243 1919

Email

pr.office@mail.sbu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Khetere Zahedi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

Street address

SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1436943415

Phone

002188045103

Email

khaterezahedi4819@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Khatere Zahedi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

Street address

SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

14369-43415

Phone

+98 21 8804 5103

Email

khaterezahedi@sbmu.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Khatere zahedi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

Street address

SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

14369-43415

Phone

+98 21 8804 5103

Email

khaterezahedi@sbmu.ac.ir

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

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Information about the timing of diagnosis of disease, The type of lesion is based on the histology, the duration of the lesion, and the anatomical location of the lesion, Patient's gender and age, response rate based on observation of complete improvement or reduction of lesion size, Information about side effects of drug

When the data will become available and for how long

The data can be accessed after the publication of the results

To whom data/document is available

People working in academic and scientific institutions

Under which criteria data/document could be used

Data can only be used to improve individuals' disease condition.

From where data/document is obtainable

Dr. Khatere Zahedi 00989132154819

khaterezahedi4819@gmail.com

What processes are involved for a request to access data/document

Request via email with complete identification data of the individual, the institution he/she works in, thorough explanation of the reason of the request. Data can be accessed after investigation of the responsible agent.

Comments