

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Investigating the effectiveness of electrochemotherapy in the treatment of squamous cell carcinoma and sarcoma and comparing the quality of life before and after treatment.

Protocol summary

Study aim

The effectiveness of electrochemotherapy in the treatment of squamous cell cancers and sarcoma and the quality of life before and after treatment will be compared.

Design

clinical trial, 4 treatment groups of ECT with intravenous and intratumoral injection, non-random sampling, but allocation in treatment groups as random allocation. It is not possible to blind the patient and the researcher, but the coded checklists will be provided to the statistical consultant and the analysis will be presented based on the group name. Each group consists of 30 tumors.

Settings and conduct

After patient referral and drug selection, patients are randomly divided into intravenous and intratumoral injection groups, and treatment is carried out in two hospitals. In the intravenous group, pulses are applied 20 minutes after the treatment, and in the intratumoral group, applied 2 minutes after the injection of bleomycin. The application of the field will continue until the complete surface of the tumor is covered, and the number of repetitions depends on the volume of the tumor. The number of treatment sessions is three sessions.

Participants/Inclusion and exclusion criteria

Entry requirements: The patient has the SCC or Sarcoma tumor. Patients for whom standard treatments did not respond or did not have a positive effect. Non-entry conditions: The patient should have metal chips, platinum, and other metals within the scope of treatment.

Intervention groups

In this research, we examine and compare two treatment groups in two types of cancer, SCC and sarcoma. Patient intervention includes: 1. Group of patients with intravenous injection of bleomycin 2. Group of patients

with the intratumor injection of bleomycin

Main outcome variables

The results of the study will be reported in the form of tumor volume, analysis of quality of life and pain, as well as treatment efficiency.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230403057807N1**

Registration date: **2023-10-12, 1402/07/20**

Registration timing: **prospective**

Last update: **2023-10-12, 1402/07/20**

Update count: **0**

Registration date

2023-10-12, 1402/07/20

Registrant information

Name

Zeinab Shankayi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-22, 1402/09/01

Expected recruitment end date

2026-08-23, 1405/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effectiveness of electrochemotherapy in the treatment of squamous cell carcinoma and sarcoma and comparing the quality of life before and after treatment.

Public title

Cancer treatment using electrical pulses and chemotherapy agent

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

1- The patient has an accessible tumor (preferably SCC sarcoma). 2- the patient is not responding to standard treatments. 3- the patient does not have comorbidity diseases such as metal chips, platinum, and other metals in the scope of treatment. 4-2 oncologists consider this type of treatment necessary for the patient.

Exclusion criteria:

The patient have metal chips, platinum and other metals near the condition of treatment.

Age

No age limit

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **120**

More than 1 sample in each individual

Number of samples in each individual: **1**

The number of accessible tumors constitutes the sample volume.

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Baqiyatallah university of medical sciences

Street address

Sheikh Bahayi Ave.

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Province

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Postal code

1435916471

Approval date

2023-02-27, 1401/12/08

Ethics committee reference number

IR.BMSU.BAQ.REC.1401.128

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

Patients with stage 4 sarcoma cancer

ICD-10 code

C46.0

ICD-10 code description

Kaposi's sarcoma of skin

2**Description of health condition studied**

Patients with stage 4 Squamous cell carcinoma cancer

ICD-10 code

C44.42

ICD-10 code description

Squamous cell carcinoma of skin of scalp and neck

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

Tumor volume

Timepoint

Before treatment, one month, three and six months after treatment

Method of measurement

MRI imaging

2**Description**

Life quality

Timepoint

before and after treatment

Method of measurement

EORTC QLQ-C30 questionnaire (European Organization for Research and Treatment of Cancer Quality of Life Questionnaire)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: patients with squamous cell tumors with intravenous injection of bleomycin and electrochemotherapy. In this intervention, chemotherapy drug bleomycin is injected intravenously with a dose of 15,000 IU/m². After 20 minutes, an electric pulse is used by a specialist doctor to penetrate the cancer cell. This treatment can be repeated three times with a maximum interval of one month.

Category

Treatment - Devices

2

Description

Intervention group: patients with squamous cell tumor with intra-tumoral injection of bleomycin drug and electrochemotherapy. In this intervention, chemotherapy drug bleomycin is injected intra-tumoral with a dose of 10,000 IU/m². After 5 minutes, an electric pulse is used by a specialist doctor to penetrate the cancer cell. This treatment can be repeated three times with a maximum interval of one month.

Category

Treatment - Devices

3

Description

Intervention group: patients with sarcoma tumor with intravenous injection of bleomycin drug and electrochemotherapy. In this intervention, chemotherapy drug bleomycin is injected intravenously with a dose of 15,000 IU/m². After 20 minutes, an electric pulse is used by a specialist doctor to penetrate the cancer cell. This treatment can be repeated three times with a maximum interval of one month.

Category

Treatment - Devices

4

Description

Intervention group: patients with intratumor injection of bleomycin drug and the electrochemotherapy with sarcoma tumor. In this intervention, chemotherapy drug bleomycin is injected intra-tumoral with a dose of 10,000 IU/m². After 5 minutes, an electric pulse is used by a specialist doctor to penetrate the cancer cell. This treatment can be repeated three times with a maximum interval of one month.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqiyatallah university of medical sciences

Full name of responsible person

Jamal Akhavan Moghadam

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Abbas Ali Imani Fooladi

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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

Bagheiat-allah 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

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Zeinab Shankayi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Physics

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

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

Tumor size before and after treatment, pain, and quality of life questionnaire will be shared.

When the data will become available and for how long

The access period starts 6 months after publishing.

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

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From where data/document is obtainable

Vice President of Research of Baqiyatallah University of Medical Sciences or Dr. Zeinab Shankayi:

z.shankayi@gmail.com

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

1- request receiving 2- Review by the university's research vice-chancellor 3- After confirmation, data will be send

Comments