Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Jun 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

recruiting

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.
City
Tehran
Province
Tehran
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-tomural injection of bleomycin drug and electrochemotherapy. In this intervention, chemotherapy drug bleomycin is injected intra-tomural 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-tomural 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

Street address
Sheikh Bahayi Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Bagheiat-allah University of Medical Sciences

Full name of responsible person
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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