Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

Phase 1 clinical trials of Trial of Intravesical Measles Virotherapy in Patients With Bladder Cancer

Protocol summary

Study aim

The main goal of this study is to present a safe and powerful method along with other effective treatment methods in bladder tumor control.

Design

The clinical trial has a control group, with parallel groups, without blinding, randomized, phase 1 on 10 patients. Excel software was used for randomization.

Settings and conduct

The procedure is like inoculating the BCG vaccine into the bladder. One week after the inoculation of the last previous treatment, 50 cc of the liquid containing the optimized measles vaccine is inoculated intravesically.

Participants/Inclusion and exclusion criteria

Inclusion criteria: • Bladder cancer has been confirmed. •The patient should be diagnosed by a urologist as a case who is resistant to BCG therapy •Not possible to perform other treatments for bladder tumor for the patient. •Age must be between 18 and 70 •not be pregnant. •Karnofsky performance score of the patient should be more than 50%. •Ability to understand and sign the consent form •Liver, kidney and bone marrow functions should be appropriate. •Liver enzymes should not be less than 2 times •Willingness to comply with all required protocol steps, •Must be willing to use contraceptive methods during the study Exit criteria: •Severe infection •History of not following the doctor's treatment orders •Sensitivity to vaccines •Immune system defect •Other investigational treatments •Pregnancy •Allergy to vaccine •Organ transplantation

Intervention groups

After receiving the standard treatments, the intervention group will receive 4 intravesical doses of the measles virus vaccine with an interval of one week. The control group received only their usual treatments and did not receive the intravesical dose of the optimized measles virus vaccine.

Main outcome variables

Weight- fever- heartburn Bleeding- pain in the abdominal area = nausea- frequent urination- blood factors- liver enzymes- changes in bladder tumors

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230903059342N1**
Registration date: **2023-10-17, 1402/07/25**
Registration timing: **registered_while_recruiting**

Last update: **2023-10-17, 1402/07/25**
Update count: **0**

Registration date

2023-10-17, 1402/07/25

Registrant information

Name

Ruhollah Dorostkar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8817 0179

Email address

r.dorost@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-23, 1402/07/01

Expected recruitment end date

2023-11-22, 1402/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Phase 1 clinical trials of Trial of Intravesical Measles Virotherapy in Patients With Bladder Cancer

Public title
Investigation of the safety and efficacy of the optimized measles virus vaccine in bladder tumor healing

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Bladder Cancer has been confirmed. The patient should be diagnosed by a urologist. It is not possible to remove the bladder for the patient. The age of the patient must be above 18 years The patient should not be pregnant. The patient's Karnofsky performance score (KPS) should be more than 50% (the patient is not disabled and does not need special assistance and care). The ability to understand and sign the consent form including the patient and one of these cases: the patient's spouse, parent. Ability to provide informed consent Be willing to comply with all required protocol steps, including providing biological samples and returning to the clinical study site for subsequent visits. Adequate performance status for treatment in the opinion of the enrolling urologist, including adequate hematological, liver, and renal function Must be willing to use contraceptive methods during the study.

Exclusion criteria:
Severe or life-threatening acute infection A history of not following the doctor's treatment orders Use of drugs that weaken the immune system Having diseases that disrupt the immune system History of organ transplantation Allergy to measles vaccine pregnancy Concomitant use of other investigational treatments Disease to other cancers such as skin that have not been fully treated.

Age
From **18 years** old

Gender
Both

Phase
1

Groups that have been masked
No information

Sample size
Target sample size: **10**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, simple randomization is used so that the referents who have the conditions to enter the study are asked to choose between the numbers 1 and 2. If he chooses number 1, he enters the control group, and if he chooses number 2, he enters the new treatment group.

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
FARHIKHTEGAN Hospital- Islamic Azad University

Street address
Tehran, at the end of Sattari, north of University Square, in front of the Central Organization

City
Tehran

Province
Tehran

Postal code
1477899679

Approval date
2023-08-15, 1402/05/24

Ethics committee reference number
IR.IAU.FARHIKHTEGANH.REC.1402.005

Health conditions studied

1

Description of health condition studied
Bladder Cancer

ICD-10 code
C67

ICD-10 code description
Malignant neoplasm of bladder

Primary outcomes

1

Description
Re-observation of bladder tumor by cystoscopy

Timepoint
Three months

Method of measurement
Cystoscopy examination of the bladder

Secondary outcomes

empty

Intervention groups

1

Description
They include patients who receive the optimized measles vaccine product in addition to the standard treatment.

Category
Treatment - Other

2

Description
Control group: Patients who receive only standard treatment.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Farhikhtegan Hospital
Full name of responsible person
Dr. Mohammad Soleimani
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kian Gen Azma Company
Full name of responsible person
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North Suhravardi, lower than Dr. Shahid Beheshti St., Sink Alley, No. 20,
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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
Kian Gen Azma Company
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact
Name of organization / entity
Bagheiat-allah University of Medical Sciences
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Position
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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
Undecided - It is not yet known if there will be a plan to make this available
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