

# 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

**Street address**

North Sattari, Islamic Azad University Square, Tehran, Iran

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Kian Gen Azma Company

**Full name of responsible person**

Dr. Ruhollah Dorostkar

**Street address**

North Suhravardi, lower than Dr. Shahid Beheshti St., Sink Alley, No. 20,

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**Email**

R.dorost@yahoo.com

**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

**Full name of responsible person**

Ruhollah Dorostkar

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Virology

**Street address**

Virology Lab. Baqiyatallah University of Medical Sciences, Nosrati Alley, Sheikh Bahai South Avenue, Mollasadra St, Vanak Sq, Tehran, Iran.

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Bagheiat-allah University of Medical Sciences

**Full name of responsible person**

Ruhollah Dorostkar

**Position**

Associate professor

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

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**City**

Tehran

**Province**

Tehran

**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