

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 May 2026

### Phase 1 Clinical Trials of Intraperitoneal Measles Virotherapy in Patients With Ovarian Cancer

#### Protocol summary

##### Study aim

Using optimized measles virus as a safe and effective method along other treatment methods to control the ovarian tumor.

##### Design

The clinical trial has a control group, with parallel groups, without blinding, randomized, phase 1 on 15 patients. Using online randomization website.

##### Settings and conduct

This investigational study is going to be conduct in Baqiyatallah hospital. The process is similar to intraperitoneal chemotherapy. The patient will receive 100 cc of the liquid containing the optimized Measles vaccine intraperitoneally within standard treatments at the same time.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1-Ovarian cancer confirmed as treatment-resistant by gynecologist 2-Age between 18 and 70 years 3-Karnofsky performance score (KPS) more than 50% (the patient should not be disabled and should not need special assistance care). 4-The ability to understand and sign the consent form by patient or patients spouse, parent or guardian Exclusion criteria: 1-Any difficulty in liver, kidney and bone marrows function. 2-Failure to cooperate in performing the required protocol, such as gathering samples and visiting for clinical study. 3-Any Infection, autoimmune disease or immune system weakness.

##### Intervention groups

The under care group will receive 4 doses of the optimized measles virus vaccine within two-week of time gap for each dose.they will receive only the standard treatments and will not receive the intraperitoneal dose of the optimized measles virus vaccine.

##### Main outcome variables

Fever and pain in the abdominal area and nausea blood factors and liver enzymes and changes in ca125 and abdominal tumors

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230903059342N2**

Registration date: **2023-12-28, 1402/10/07**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-12-28, 1402/10/07**

Update count: **0**

##### Registration date

2023-12-28, 1402/10/07

##### 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

2023-12-22, 1402/10/01

##### Expected recruitment end date

2024-07-22, 1403/05/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Phase 1 Clinical Trials of Intraperitoneal Measles Virotherapy in Patients With Ovarian Cancer

## Public title

Investigating the treatment of ovarian cancer by optimized measles vaccine

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Confirmation of the patient's ovarian cancer by a gynecologist  
Diagnosis of disease as drug resistance  
Patient age 18 to 70  
Absence of pregnancy. The Karnofsky performance score (KPS) of the patient is 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 by the patient and one of these cases: the patient's spouse, parent or guardian.  
Proper functioning of liver, kidney and bone marrow  
Complying with all protocol steps including sample submission and returning to the clinical study site for subsequent visits  
Absence of autoimmune diseases or diseases of the immune system

### Exclusion criteria:

Life-threatening acute infection  
Absence of any previous record that describes the doctor's treatment and orders were not followed by patient.  
Using drugs that weaken the immune system  
Affected by any diseases that disturb the immune system  
Having any previous record of organ transplantation  
Allergy to measles vaccine  
pregnancy  
Using other investigational treatments at the same time  
Being affected by other cancers

## Age

From **18 years** old to **70 years** old

## Gender

Female

## Phase

1

## Groups that have been masked

*No information*

## Sample size

Target sample size: **15**

## Randomization (investigator's opinion)

Randomized

## Randomization description

The randomization method is going to be done by the method of random blocks of 6 random strings with a length of 15 coincidences with a ratio of 2 to 1. This string is created by one of the online randomization software. In order to hide the randomization, the method of closed envelopes will be used.

## 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

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

##### City

Tehran

##### Province

Tehran

##### Postal code

1435916471

#### Approval date

2023-11-29, 1402/09/08

#### Ethics committee reference number

IR.BMSU.REC.1402.070

## Health conditions studied

### 1

#### Description of health condition studied

Ovarian cancer

#### ICD-10 code

C56

#### ICD-10 code description

Malignant neoplasm of ovary

## Primary outcomes

### 1

#### Description

Fever

#### Timepoint

Hourly in the first 24 hours and then daily up to 7 days

#### Method of measurement

Thermometer

### 2

#### Description

Examining changes in the patient's heart condition

#### Timepoint

Hourly after the start of treatment for up to 7 days

#### Method of measurement

Electrocardiogram

### 3

#### Description

Examining changes in the patient's breathing status

**Timepoint**

Hourly in the first 24 hours and then daily up to 7 days

**Method of measurement**

pulse oximeter

**4****Description**

Examining the amount of ca 125 cancer antigen in the blood

**Timepoint**

Weekly until 3 months after the end of treatment

**Method of measurement**

Blood test

**5****Description**

Examination of tumors of the abdominal cavity

**Timepoint**

Weekly until 3 months after the end of treatment

**Method of measurement**

Sonography

**Secondary outcomes**

empty

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

Intervention group: includes patients who, in addition to standard treatment, receive the optimized measles vaccine that designed and optimized by Baqiyatullah university intraperitoneally in four doses with an interval of two weeks for each dose. At the same time as being treated with the optimized measles vaccine, the patient receives standard treatments including chemotherapy with cisplatin and immunotherapy with Avastin. In fact, the intervention is in the form of adjuvant therapy.

**Category**

Treatment - Other

**2****Description**

Control group: patients who receive only standard treatment including chemotherapy with Cisplatin and immunotherapy with Avastin

**Category**

Other

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Baqiyatallah Hospital

**Full name of responsible person**

Seyedeh Razieh Hashemi

**Street address**

Baqiyatallah Hospital, Mollasadra Ave., Vanak Square  
., Tehran-Iran

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**Province**

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**Postal code**

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**Phone**

+98 21 8805 0435

**Email**

R.dorost@yahoo.com

**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,

**City**

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1577943613

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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

**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**

Seyedeh Razieh Hashemi

**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Gynecology and Obstetrics

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

Bagheiat-allah University of Medical Sciences

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Ruhollah Dorostkar

**Position**

Associate professor

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Ph.D.

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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