

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 2026

### The first phase of the trial to investigate the safety and efficacy of intratumoral administration of optimized measles virus in patients with pancreatic cancer

#### Protocol summary

##### Study aim

En Using optimized measles virus as a safe and effective method along other treatment methods to control the pancreatic 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 Gastroenterology and Liver Research Center and Baqiyatallah hospital. The patient will receive 5 cc of the liquid containing the optimized Measles vaccine intratumorally within standard treatments at the same time.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1-Ovarian cancer confirmed as treatment-resistant by gastroenterologist 2-Age between 18 and 85 years . 3-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 intratumorally every week. Control group will receive only the standard treatments and will not receive the the optimized measles virus vaccine intratumorally.

##### Main outcome variables

Fever, pain in the abdominal area, nausea, blood factors, liver enzymes, changes in CEA andCA19-9 and tumor size

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230903059342N3**

Registration date: **2024-10-19, 1403/07/28**

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

Last update: **2024-10-19, 1403/07/28**

Update count: **0**

##### Registration date

2024-10-19, 1403/07/28

##### 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

2024-09-22, 1403/07/01

##### Expected recruitment end date

2025-03-19, 1403/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

The first phase of the trial to investigate the safety and efficacy of intratumoral administration of optimized measles virus in patients with pancreatic cancer

## Public title

Evaluation of pancreatic cancer treatment by optimized measles vaccine

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Confirmation of the patient's cancer by a gastroenterologist Patient age 18 to 85 Absence of pregnancy Proper functioning of liver, kidney and bone marrow The ability to understand and sign the consent form by the patient and one of these cases: the patient's spouse, parent or guardian. 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 nor followed by patient. Using drugs that weaken the immune system Affected by any diseases that disturbs the immune system Having any previous record of organ transplantation Allergy to measles vaccine pregnancy Using other investigational treatments at the same time

## Age

From **18 years** old to **85 years** old

## Gender

Both

## 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 in the Research Institute of Gastrointestinal and Liver Diseases of Shahid Beheshti

##### Street address

Institute of Gastrointestinal and Liver Diseases, In the yard of Taleghani Hospital, Arabi St., Yemen St., Chamran Highway

##### City

Tehran

##### Province

Tehran

##### Postal code

1985717413

#### Approval date

2024-05-15, 1403/02/26

#### Ethics committee reference number

IR.SBMU.RIGLD.REC.1403.026

## Health conditions studied

### 1

#### Description of health condition studied

pancreatic cancer

#### ICD-10 code

C25.9

#### ICD-10 code description

Malignant neoplasm of pancreas, unspecified

## 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 CEA & CA19-9 cancer antigen in the blood

##### **Timepoint**

Weekly until 3 months after the end of treatment

##### **Method of measurement**

Blood test

#### 5

##### **Description**

Examination of tumor size

##### **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 weekly. At the same time as being treated with the optimized measles vaccine, the patient receives standard treatments including chemotherapy and immunotherapy. In fact, the intervention is in the form of adjuvant therapy.

##### **Category**

Treatment - Other

#### 2

##### **Description**

Control group: They receive only standard treatment including chemotherapy and immunotherapy and no intervention is done in their standard treatment.

##### **Category**

Other

## **Recruitment centers**

#### 1

##### **Recruitment center**

###### **Name of recruitment center**

Baqiyatallah Hospital

###### **Full name of responsible person**

Mohammad Ali Abyazi

###### **Street address**

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

###### **City**

Tehran

###### **Province**

Tehran

###### **Postal code**

1435916471

###### **Phone**

+98 21 8805 0435

###### **Email**

R.dorost@yahoo.com

###### **Web page address**

#### 2

##### **Recruitment center**

###### **Name of recruitment center**

Research Institute of Gastrointestinal and Liver Diseases, Shahid Beheshti University of Medical Sci

###### **Full name of responsible person**

Amir Sadeghi

###### **Street address**

Digestive and Liver Diseases Research Institute of Shahid Beheshti University of Medical Sciences, in the yard of Taleghani Hospital, Arabi Street, Yemen Street, Chamran Highway

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## **Sponsors / Funding sources**

#### 1

##### **Sponsor**

###### **Name of organization / entity**

Shahid Beheshti University of Medical Sciences

###### **Full name of responsible person**

Afshin Zarghi

###### **Street address**

Digestive and Liver Diseases Research Institute of Shahid Beheshti University of Medical Sciences, in the yard of Taleghani Hospital, Arabi Street, Yemen Street, Chamran Highway

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###### **Email**

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**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

No

**Title of funding source**

Research Assistant of Shahid Beheshti University of Medical Sciences

**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**

Persons

**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

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Bagheiat-allah University of Medical Sciences

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**Position**

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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