

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 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

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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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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

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Name of organization / entity

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Full name of responsible person

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Position

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Latest degree

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Person responsible for updating data

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Name of organization / entity

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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