

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

A clinical trial of the first phase of evaluating the safety and efficacy of the optimized intraperitoneal measles virus vaccine in patients with malignant ascites.

Protocol summary

Study aim

Use of optimized measles virus as a safe and effective method for improving malignant ascites

Design

The clinical trial has a control group, with parallel groups, without blinding, randomized, phase 1 on 20 patients. Using online randomization website.

Settings and conduct

This investigational study is going to be conduct in Baqiyatallah hospital. The patient will receive 5 cc of the liquid containing the optimized Measles vaccine intraperitoneal within standard treatments at the same time.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Confirmation of malignant pleural effusion 2- Over 18 years old 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 patient receives the optimized measles virus vaccine intraperitoneal while receiving standard treatments. The control group receives only standard treatments and does not receive the intraperitoneal treatment dose of the optimized measles virus vaccine.

Main outcome variables

Fever, Abdominal pain, blood oxygen index, respiratory status, nausea, blood factors, liver enzymes, cancer markers

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230903059342N6**

Registration date: **2026-05-30, 1405/03/09**

Registration timing: **prospective**

Last update: **2026-05-30, 1405/03/09**

Update count: **0**

Registration date

2026-05-30, 1405/03/09

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

Not yet recruiting

Funding source

Expected recruitment start date

2026-06-21, 1405/03/31

Expected recruitment end date

2026-12-21, 1405/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial of the first phase of evaluating the safety

and efficacy of the optimized intraperitoneal measles virus vaccine in patients with malignant ascites.

Public title

Evaluation of the safety and efficacy of an optimized measles virus vaccine in patients with malignant ascites

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with malignant ascites Patient age between 18 and 80 years 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 **80 years** old

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **20**

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 20 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 Research of the Educational and Therapeutic Center of Baqiyatullah Al-Azam

Street address

Mollasadra st, Vanak sq, Sheykh bahayi st, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1435915371

Approval date

2025-01-19, 1403/10/30

Ethics committee reference number

IR.BMSU.BAQ.REC.1403.227

Health conditions studied

1

Description of health condition studied

Malignant ascites

ICD-10 code

R18.0

ICD-10 code description

Malignant ascites

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

Examining changes in the patient's heart condition

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

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In addition to standard treatment, patients receive the optimized measles vaccine product designed and optimized by Baqiyatallah University intraperitoneal. Simultaneously with treatment with the optimized measles vaccine, patients receive their standard treatments including chemotherapy and immunotherapy. In fact, the intervention is in the form of adjuvant therapy.

Category

N/A

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

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Abbas Ali Imani Fooladi

Street address

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

Bagheiat-allah University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

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

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Full name of responsible person

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Position

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

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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