

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 2026

### Evaluation of the Effect of Intrapleural Administration of an Optimized Measles Vaccine on Dyspnea Improvement and Effusion Volume in Patients with Malignant Pleural Effusion

#### Protocol summary

##### Study aim

Use of optimized measles virus as a safe and effective method in improving dyspnea and effusion volume in patients with malignant pleural effusion

##### Design

The clinical trial has a control group, with parallel groups, without blinding, randomized, phase 1 on 10 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 intratumorally 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 intrapleurally while receiving standard treatments. The control group receives only standard treatments and does not receive the intrapleural treatment dose of the optimized measles virus vaccine.

##### Main outcome variables

Fever, chest 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: **IRCT20230903059342N5**  
Registration date: **2026-05-23, 1405/03/02**  
Registration timing: **prospective**

Last update: **2026-05-23, 1405/03/02**

Update count: **0**

##### Registration date

2026-05-23, 1405/03/02

##### 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

2026-09-22, 1405/06/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of the Effect of Intrapleural Administration of

an Optimized Measles Vaccine on Dyspnea Improvement and Effusion Volume in Patients with Malignant Pleural Effusion

#### Public title

Study of helping to improve shortness of breath and effusion volume in patients with malignant pleural effusion

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Patients with malignant pleural effusion Patient age over 18 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

#### Gender

Both

#### Phase

1

#### Groups that have been masked

No information

#### Sample size

Target sample size: 10

#### 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

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

##### City

Tehran

##### Province

Tehran

##### Postal code

1435915371

#### Approval date

2026-05-17, 1405/02/27

#### Ethics committee reference number

IR.BMSU.BAQ.REC.1405.002

## Health conditions studied

### 1

#### Description of health condition studied

Malignant pleural effusion

#### ICD-10 code

J91.0

#### ICD-10 code description

Malignant pleural effusion

## 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 intrapleurally. 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

Abbas Samim

#### Street address

Tehran, Molla Sadra Street, the intersection of South Sheikh Bahai Street

#### City

Tehran

#### Province

Tehran

#### Postal code

1435915371

#### Phone

+98 21 85554

#### Email

R.dorost@yahoo.com

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Bagheiat-allah University of Medical Sciences

#### Full name of responsible person

Dr. Ruhollah Dorostkar

#### Street address

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

#### City

Tehran

#### Province

Tehran

#### Postal code

1577943613

#### Phone

+98 21 8817 0179

#### 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

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.

#### City

Tehran

#### Province

Tehran

#### Postal code

1435916471

#### Phone

+98 21 8817 0179

#### Fax

#### Email

R.dorost@yahoo.com

## 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

#### Latest degree

Ph.D.

**Other areas of specialty/work**

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**Person responsible for updating data**

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**Phone**

+98 21 8817 0179

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**Email**

R.dorost@yahoo.com

**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