

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Aug 2026

The first phase and second of the trial investigating the safety and efficacy of Intratumorally optimized measles vaccine in patients with Neuroblastoma cancer

Protocol summary

Study aim

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

Design

The clinical trial has a control group, with parallel groups, without blinding, randomized, phase 1 and 2 on 10 patients. Using online randomization website.

Settings and conduct

This investigational study is going to be conducted in Shahid Sadoughi Hospital, Yazd and Baqiyatallah Hospital. The patient will receive 2 cc of the liquid containing the optimized Measles vaccine intratumorally within standard treatments at the same time.

Participants/Inclusion and exclusion criteria

Ovarian cancer confirmed as treatment-resistant by Pediatric cancer specialist 2-Age between 2 and 21 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 2 doses of the optimized measles virus vaccine intratumorally 4 weeks apart. Control group will receive only the standard treatments and will not receive the optimized measles virus vaccine intratumorally.

Main outcome variables

Fever, pain in the abdominal area, nausea, blood factors, liver enzymes and tumor size

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230903059342N4**

Registration date: **2025-11-11, 1404/08/20**

Registration timing: **prospective**

Last update: **2025-11-11, 1404/08/20**

Update count: **0**

Registration date

2025-11-11, 1404/08/20

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

recruiting

Funding source

Expected recruitment start date

2025-11-22, 1404/09/01

Expected recruitment end date

2027-11-22, 1406/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The first phase and second of the trial investigating the

safety and efficacy of Intratumorally optimized measles vaccine in patients with Neuroblastoma cancer	
Public title	Evaluation of Neuroblastoma cancer treatment by optimized measles vaccine
Purpose	Treatment
Inclusion/Exclusion criteria	Inclusion criteria: Patient age 2 to 21 The patient must be considered by a pediatric oncologist to be refractory to conventional treatments or for which there is no standard treatment. The non-central nervous system solid tumor has been confirmed by a histologist. 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 Using other investigational treatments at the same time
Age	From 2 years old to 21 years old
Gender	Both
Phase	1-2
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	
<u>1</u>	
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	2025-10-27, 1404/08/05
Ethics committee reference number	IR.BMSU.REC.1404.106
Health conditions studied	
<u>1</u>	
Description of health condition studied	Neuroblastoma Cancer
ICD-10 code	C47
ICD-10 code description	Malignant neoplasm of peripheral nerves and autonomic nervous system
Primary outcomes	
<u>1</u>	
Description	Fever
Timepoint	Hourly in the first 24 hours and then daily up to 7 days
Method of measurement	Thermometer
<u>2</u>	
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
<u>3</u>	
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

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Description

Examination of tumor size

Timepoint

Weekly until 6 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 intraperitoneally in 2 doses 4 weeks apart. 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

Dr Hassan Abolghasemi

Street address

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

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Province

Tehran

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1435915371

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Email

R.dorost@yahoo.com

2

Recruitment center

Name of recruitment center

Shahid Sadoughi Yazd Hospital

Full name of responsible person

Dr Ali Reza Jenabzade

Street address

Shahid Sadoughi Hospital, Avicenna Blvd., Yazd, Iran.

City

Yazd

Province

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Dr Abbas ali Imanifooladi

Street address

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

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Province

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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

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

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Full name of responsible person

Ruhollah Dorostkar

Position

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Latest degree

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Person responsible for updating data

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Email

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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