Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Nov 2026

Phase 1 Clinical Trials of Intraperitoneal Measles Virotherapy in Patients With Ovarian Cancer

Protocol summary

Study aim

Using optimized measles virus as a safe and effective method along other treatment methods to control the ovarian 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 Baqiyatallah hospital. The process is similar to intraperitoneal chemotherapy. The patient will receive 100 cc of the liquid containing the optimized Measles vaccine intraperitoneally within standard treatments at the same time.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1-Ovarian cancer confirmed as treatment-resistant by gynecologist 2-Age between 18 and 70 years 3-Karnofsky performance score (KPS) more than 50% (the patient should not be disabled and should not need special assistance care). 4-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 within two-week of time gap for each dose.they will receive only the standard treatments and will not receive the intraperitoneal dose of the optimized measles virus vaccine.

Main outcome variables

Fever and pain in the abdominal area and nausea blood factors and liver enzymes and changes in ca125 and abdominal tumors

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230903059342N2**
Registration date: **2023-12-28, 1402/10/07**
Registration timing: **registered_while_recruiting**

Last update: **2023-12-28, 1402/10/07**
Update count: **0**

Registration date

2023-12-28, 1402/10/07

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

2023-12-22, 1402/10/01

Expected recruitment end date

2024-07-22, 1403/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Phase 1 Clinical Trials of Intraperitoneal Measles Virotherapy in Patients With Ovarian Cancer

Public title
Investigating the treatment of ovarian cancer by optimized measles vaccine
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Confirmation of the patient's ovarian cancer by a gynecologist Diagnosis of disease as drug resistance Patient age 18 to 70 Absence of pregnancy. The Karnofsky performance score (KPS) of the patient is more than 50% (the patient is not disabled and does not need special assistance and care). The ability to understand and sign the consent form by the patient and one of these cases: the patient's spouse, parent or guardian. Proper functioning of liver, kidney and bone marrow 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 Being effected by other cancers
Age
From **18 years** old to **70 years** old
Gender
Female

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 of Baqiyatallah University of Medical Sciences
Street address
Baqiyatallah University of Medical Sciences, Nosrati Alley, Sheikh Bahai South Avenue, Mollasadra St, Vanak Sq, Tehran, Iran.
City
Tehran
Province
Tehran
Postal code
1435916471
Approval date
2023-11-29, 1402/09/08
Ethics committee reference number
IR.BMSU.REC.1402.070

Health conditions studied

1

Description of health condition studied
Ovarian cancer
ICD-10 code
C56
ICD-10 code description
Malignant neoplasm of ovary

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 ca 125 cancer antigen in the blood
Timepoint
Weekly until 3 months after the end of treatment
Method of measurement
Blood test

5

Description
Examination of tumors of the abdominal cavity
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 with an interval of two weeks for each dose. At the same time as being treated with the optimized measles vaccine, the patient receives standard treatments including chemotherapy with cisplatin and immunotherapy with Avastin. In fact, the intervention is in the form of adjuvant therapy.
Category
Treatment - Other

2

Description
Control group: patients who receive only standard treatment including chemotherapy with Cisplatin and immunotherapy with Avastin
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Baqiyatallah Hospital
Full name of responsible person
Seyedeh Razieh Hashemi
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

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kian Gen Azma Company
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
Kian Gen Azma Company
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
Industry

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
Seyedeh Razieh Hashemi
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Baqiyatallah Hospital, Mollasadra Ave., Vanak Square ., Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1435916471
Phone
+98 21 8805 0435
Fax
Email
R.dorost@yahoo.com

Person responsible for updating data

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

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