Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jul 2026

Evaluation of the safety of intrathecal injection of activated allogenic Natural Killer (NK) cells in pediatrics with brain gliomas; A phase I clinical trial

Protocol summary

Study aim
Evaluation the safety of intrathecal injection of activated allogenic NK cells in pediatrics with brain gliomas

Design
A phase I, open label, non control, non randomized trial in 10 eligible patients

Settings and conduct
Patients will be admitted to Rasoul Akram hospital and in period between end of radiotherapy and start of chemotherapy, or in intervals between chemotherapy courses will receive five injections. Five more injections will be planned in cases of response to the treatment.

Participants/Inclusion and exclusion criteria
patients with diagnosis of brain stem glioma, DIPG, unresectable glioma, and relapsed-refractory glioma which have the following inclusion criteria: 1. Age between 3 to 18 years old 2. Hemoglobin level above 10 gr/deciliter of blood 3. Absolute granulocyte count (AGC) above 1500 per microliter of blood 4. Platelet count above 100000 per microliter of blood 5. Lansky/Karnofsky performance score above 60 6. INR below 2 and PTT less than 1/5 times of maximum normal value 7. Plasma Bilirubin level less than 1/5 times of maximum normal value 8. Plasma hepatic transaminases (ALT and AST) level less than 2/5 times of maximum normal value 9. Plasma Creatinine level less than 1/5 times of maximum normal value the exclusion criteria are: 1.evidence of radio necrosis in MRI or MRS 2. intolerance of new treatment due to emergency condition 3. rupture of cerebral shunt or unable to perform a lumbar puncture (LP) 4. history of other malignancies 5. history of any immunodeficiency diseases or any immune compromising conditions 6. occurrence of new neurologic lesion after first injection

Intervention groups
40-50 million activated allogenic NK cells will be injected intrathecally every week till five injection. In cases of response to the treatment, five more injections will be planned

Main outcome variables
Safety of intrathecal injection of NK cells

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170122032121N6**
Registration date: **2021-11-19, 1400/08/28**
Registration timing: **registered_while_recruiting**

Last update: **2022-10-22, 1401/07/30**
Update count: **1**

Registration date
2021-11-19, 1400/08/28

Registrant information

Name
Marzieh Ebrahimi

Name of organization / entity
Royan Institute

Country
Iran (Islamic Republic of)

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+98 23562516

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-10-17, 1400/07/25

Expected recruitment end date
2022-10-22, 1401/07/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the safety of intrathecal injection of activated allogenic Natural Killer (NK) cells in pediatrics with brain gliomas; A phase I clinical trial

Public title
NK cell therapy in pediatrics with brain glioma
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
patients with diagnosis of brain stem glioma, DIPG, unresectable glioma, and relapsed-refractory glioma Age between 3 to 18 years old Hemoglobin level above 10 gr/deciliter of blood Absolute granulocyte count (AGC) above 1500 per microliter of blood Platelet count above 100000 per microliter of blood Lansky (for under 16 years old) or Karnofsky (for above 16 years old) performance score above 60 INR below 2 and PTT less than 1/5 times of maximum normal value Plasma Bilirubin level less than 1/5 times of maximum normal value Plasma hepatic transaminases (ALT and AST) level less than 2/5 times of maximum normal value Plasma Creatinine level less than 1/5 times of maximum normal value Informed consent of parents or legal attendance
Exclusion criteria:
evidence of radio necrosis in MRI or MRS intolerance of new treatment due to emergency condition rupture of cerebral shunt or unable to perform a lumbar puncture (LP) history of other malignancies history of any immunodeficiency diseases or any immune compromising conditions occurrence of new neurologic lesion after first injection
Age
From **3 years** old to **18 years** old
Gender
Both

Phase
1
Groups that have been masked
No information
Sample size
Target sample size: **10**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Royan institute ethics committee
Street address
Royan ethics committee, Royan alley, Hafez street, Banihashem square, Banihashem street, Resalat highway, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1665659911
Approval date
2021-09-21, 1400/06/30
Ethics committee reference number
IR.ACECR.ROYAN.REC.1400.077

Health conditions studied

1

Description of health condition studied
Brain glioma
ICD-10 code
C71
ICD-10 code description
Malignant neoplasm of brain

Primary outcomes

1

Description
Safety of intrathecal injection of Natural Killer (NK) cells
Timepoint
safety will be measured after each injection till 24 hour in hospital for acute adverse events. Other adverse events will be recorded in periodical follow up in 1, 3, 6, and 12 month after the last injection
Method of measurement
Common Terminology Criteria for Adverse Events (CTCAEs) checklist

Secondary outcomes

1

Description
Change of tumor size
Timepoint
Tumor size will be measured before the first injection and after fifth and tenth injection it will be measured again. 3 month, 6 month and 12 month after the last injection the

size will be measured ordinally.

Method of measurement

MRI (with and without contrast and DWI method) and MRS

2

Description

Overall survival and progression-free survival

Timepoint

At the end of the study the survivals will be measured for patients

Method of measurement

Kaplan-Meier method

3

Description

Cerebrospinal fluid (CSF) analysis (cytokine changes, hematology, and biochemistry)

Timepoint

Before each injection, samples of CSF will be taken and will sent to lab for analysis

Method of measurement

ELISA, Spectrophotometry, microscopic study

Intervention groups

1

Description

Intervention group: 40-50 million activated allogenic NK cells will be injected intrathecally every week till five injection. In cases of response to the treatment, five more injections will be planned.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoul Akram hospital

Full name of responsible person

Mohammad Faranoush

Street address

Pediatric oncology ward, floor 4, Rasoul Akram hospital, Niayesh street, Shahr Ara street, Sattar Khan vicinity, Tehran, Iran

City

Tehran

Province

Tehran

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1445613131

Phone

+98 21 6652 5328

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faranoush47@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Royan institute

Full name of responsible person

Marzieh Ebrahimi

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Royan institute, Hafez street, Banihashem square, Banihashem street, Resalat highway, Tehran, Iran

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marzieh.ebrahimi@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Royan institute

Proportion provided by this source

10

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

2

Sponsor

Name of organization / entity

Kian Immune Cell company

Full name of responsible person

Hassan Salehi Moghaddam

Street address

No 6, RITAC center, Keshvari avenue, Banihashem square

City

Tehran

Province

Tehran

Postal code

1665813339

Phone

+98 21 2233 8248

Email

kiacell.immune@gmail.com

Web page address

https://kiacell-immune.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kian Immune Cell company

Proportion provided by this source

90

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

Royan institute

Full name of responsible person

Hamid Mahdizadeh

Position

Research assistant

Latest degree

Medical doctor

Other areas of specialty/work

Immunology

Street address

Kian immune cell company, first floor, Royan RITAC center, Number 6, Keshvari alley, Banihashem square, Banihashem street, Resalat highway, Tehran, Iran

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Royan institute

Full name of responsible person

Hamid Mahdizadeh

Position

Research assistant

Latest degree

Medical doctor

Other areas of specialty/work

Immunology

Street address

Kian immune cell company, first floor, Royan RITAC center, Number 6, Keshvari alley, Banihashem square, Banihashem street, Resalat highway, Tehran, Iran

City

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mahdizadehmd@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Royan institute

Full name of responsible person

Hamid Mahdizadeh

Position

Research assistant

Latest degree

Medical doctor

Other areas of specialty/work

Immunology

Street address

Kian immune cell company, first floor, Royan RITAC center, Number 6, Keshvari alley, Banihashem square, Banihashem street, Resalat highway, Tehran, Iran

City

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Postal code

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Phone

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Email

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Not applicable

Title and more details about the data/document

After concealment of personal information of participants, data of eligibility, CRFs and measured outcomes can be shared in case of request.

When the data will become available and for how long

After publishing results in a scientific journal with no deadline

To whom data/document is available

Just to academic PIs

Under which criteria data/document could be used

Any usage of data should be consulted and approved by the PIs (Dr.Ebrahimi and Dr.Faranoush)

From where data/document is obtainable

Applicant should send an e-mail to Dr.Mahdizadeh and propose their detailed requirements of the study data

What processes are involved for a request to access data/document

After sending an e-mail to Dr.Mahdizadeh, he will assess the authenticity of the applicant in almost 2 weeks. Then he will plan a meeting (visual or attendance) for the applicant with Dr.Ebrahimi and Dr.Faranoush in next month. The applicant can obtain approval of data sharing in this meeting and the data will be sent in next 14 days.

Comments