

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Immunotherapy of pediatric patients with brain tumor using autologous tumor - lysate pulsed dendritic cells in a phase I/II clinical trial

Protocol summary

Summary

Dendritic cells are the major antigen presenting cells which stimulate naive as well as memory T cells to mount antitumor immunity. Because of inhibition of immune responses in tumor microenvironment, it is believed that ex vivo generation of tumor antigen pulsed mature DCs and reinfusion to tumor bearing patients will result in tumor specific immune responses. To address this issue, in this phase I/II clinical trial, 20 patients with pediatric brain tumor will be vaccinated with autologous tumor antigen pulsed DCs three times and immunological and clinical responses as well as side effects will be assayed in a three month follow up.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016080829257N1**
Registration date: **2016-11-04, 1395/08/14**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-11-04, 1395/08/14

Registrant information

Name

Nowruz Delirezh

Name of organization / entity

Urmia University

Country

Iran (Islamic Republic of)

Phone

+98 44 3344 0198

Email address

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Recruitment status

Recruitment complete

Funding source

Ministry of Health and Medical Education

Expected recruitment start date

2017-01-01, 1395/10/12

Expected recruitment end date

2019-01-01, 1397/10/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Immunotherapy of pediatric patients with brain tumor using autologous tumor - lysate pulsed dendritic cells in a phase I/II clinical trial

Public title

Immunotherapy of pediatric brain cancer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Brain tumor without metastases or recurrence; glioma; meduloblastoma; CD4>350 cell/mm; 3-18 months ≤ age ≤15 years; 10Kg ≤Weight; Confirmation of informed consent; Normal serum tests; Immunotherapy should be started at least 3 wks after last chemo or radiotherapy course Exclusion criteria: Cardiovascular-pulmonary diseases; Hepatitis B, C or HIV infections; tumor pressure on spinal cord; Patient who will need chemo or radiotherapy during immunotherapy; 470ms≤Improved QT; ECG disorders; corticosteroid administration

Age

From **1 year** old to **15 years** old

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: 20

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

Urmia University of Medical Science Ethic Committee

Street address

Resalat Bvd, Urmia University of Medical Science
Campus

City

Urmia

Postal code

5714783734

Approval date

2016-03-01, 1394/12/11

Ethics committee reference number

IR umsu.rec.1394.452

Health conditions studied

1

Description of health condition studied

neoplasm

ICD-10 code

C71.2

ICD-10 code description

Malignant Neoplasm of Temporal Lobe

Primary outcomes

1

Description

side effects

Timepoint

72 hrs

Method of measurement

NCI COMMON TOXICITY CRITERIA

Secondary outcomes

1

Description

Clinical and Immunological Responses

Timepoint

At least one year

Method of measurement

Flow Cytometry, Elisa, Overall Survival, Progression Free Survival

Intervention groups

1

Description

Generation of immature dendritic cells from isolated monocytes of patients, pulsing of DCs with autologous tumor lysate, induction of maturation in DCs, reinfusion of mature DCs to patient This study is planned as phase I/II clinical trial, so no control group is considered

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Urmia University of Medical Science

Full name of responsible person

Dr Nowruz Delirezeh

Street address

Institute of Biotechnology

City

Urmia

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Urmia University of Medical Science

Full name of responsible person

Dr Iraj Mohebbi

Street address

Vice President of Research

City

Urmia

Grant name

پروژه ایمنوتراپی سرطان مغز

Grant code / Reference number

14000245577

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

Yes

Title of funding source

Urmia University of Medical Science

Proportion provided by this source

100

Public or private sector*empty***Domestic or foreign origin***empty***Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding***empty***Person responsible for general inquiries****Contact****Name of organization / entity**

Institute of Biotechnology, Urmia University

Full name of responsible person

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Chairman

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Sharing plan**Deidentified Individual Participant Data Set (IPD)***empty***Study Protocol***empty***Statistical Analysis Plan***empty***Informed Consent Form***empty***Clinical Study Report***empty***Analytic Code***empty***Data Dictionary***empty*