Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jun 2026

Evaluation of Efficacy and Possible Side Effects of Human Polyclonal Antibodies (IVIg) of Medvac Biopharma Co. in the Treatment of Patients with Primary Immunodeficiency disorder (PID)

Protocol summary

Study aim
Comparison of the effects and side effects of MedVac IVIg injection with Biotest IVIg among patients with Primary Immunodeficiency (PID) referred to Hazrat Rasoul Akram Hospital and Mofid Children's Hospital in Tehran

Design
Randomized, Open label, Cross-over, Clinical trial

Settings and conduct
Eligible PID patients after recruiting to the trial, in Mofid Children's Hospital and Hazrat Rasool Akram Hospital in Tehran, 25 patients in each arm, will be subjected to intervention by one of the two types of IVIg and followed for 4 weeks, after the end of the treatment period and completion of Wash out period, enters the opposite arm in a cross-sectional way and will receive the alternative type of IVIg and will be followed up for another 4 weeks.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: 1- 2-40 years old patients with PID who weigh 10 kg or more and have received at least 6 months of IVIg the recruitment 2- Willingness to cooperate and obtain written consent Exclusion Criteria: 1- Patients with secondary immunodeficiency, newly diagnosed PID and without treatment, dysglobunemia, IgA deficiency, HIV, hepatitis A,B,C or a history of these diseases 2 -History of hypersensitivity to IVIg or other forms of Ig or history of thrombotic complications of IVIg / History of severe seizures, migraines and DVT 3- Concomitant use of corticosteroids, chemotherapy, immunosuppressive drugs 4- Chronic kidney and liver diseases, Nephrotic syndrome and various malignancies 5- Acute bacterial infection in the last 7 days

Intervention groups
Infusion of 600 mg/kg IVIg produced by MedVac and Biotest every 4 weeks

Main outcome variables
Serum IgG level changes before and one hour after IVIg injection

General information

Reason for update
According to the opinions of the Clinical Studies Committee of the Food and Drug Organization, minor amendments have been made to the protocol and the Ethics Committees in the Research have been notified.

Acronym

IRCT registration information
IRCT registration number: **IRCT20101012004920N9**
Registration date: **2021-02-23, 1399/12/05**
Registration timing: **prospective**

Last update: **2021-08-01, 1400/05/10**
Update count: **1**

Registration date
2021-02-23, 1399/12/05

Registrant information

Name
Ramin Heshmat

Name of organization / entity
Chronic Diseases Research Center

Country
Iran (Islamic Republic of)

Phone
+98 21 8822 0086

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rheshmat@tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-09-01, 1400/06/10

Expected recruitment end date

2022-08-31, 1401/06/09

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of Efficacy and Possible Side Effects of Human Polyclonal Antibodies (IVIg) of Medvac Biopharma Co. in the Treatment of Patients with Primary Immunodeficiency disorder (PID)

Public title
Evaluation of the effect of Medvac IVIg on PID

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with congenital or primary immunodeficiency of 2-40years old who weigh 10 kg or more. Previously confirmed Congenital or Primary Immunodeficiency which have received at least six months of IVIg treatment Willingness to cooperate and obtain informed written consent from the patient, parent or legal guardian of the child

Exclusion criteria:
Patients with secondary immunodeficiency, newly diagnosed primary immunodeficiency and without treatment, dysglobunemia History of hypersensitivity to IVIg or other injectable forms of Ig or history of thrombotic complications of IVIg treatment Patients with IgA deficiency Concomitant use of corticosteroids, chemotherapy, immunosuppressive drugs Patients with HIV, hepatitis A, B, C or a history of these diseases History of severe seizures or migraines Chronic kidney diseases, liver and various malignancies Nephrotic syndrome DVT history Acute bacterial infection in the last 7 days

Age
From **2 years** old to **40 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
After selection of eligible patients and obtaining informed consent, a unique code will be assigned to each patient and randomized in two treatment groups. The randomization method will be Permuted Balanced Block Randomization. Blocks of 4 will be selected according to the number of intervention groups.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Iran University of Medical Sciences Ethical Committee

Street address
Hemmat Highway, Iran University of Medical Sciences

City
Tehran

Province
Tehran

Postal code
1449614535

Approval date
2021-02-17, 1399/11/29

Ethics committee reference number
IR.IUMS.REC.1399.1285

2

Ethics committee

Name of ethics committee
Biomedical Research Ethics Committee, Research Instutute for Children Health, Shahid Beheshti Univer

Street address
Mofid Hospital, Shariati St.

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Tehran

Province
Tehran

Postal code
1546815514

Approval date
2021-03-01, 1399/12/11

Ethics committee reference number
IR.SBMU.RICH.EC.1400.008

Health conditions studied

1

Description of health condition studied
Primary immunodeficiency disorder

ICD-10 code
D84.9

ICD-10 code description
D84.9 is a billable/specific ICD-10-CM code that can be used to indicate a diagnosis for reimbursement purposes.

Primary outcomes

1

Description
Serum IgG level changes before and after IVIg injection
Timepoint
Before intervention and one hour after intervention
Method of measurement
ELISA serum IgG level measurement kit

Secondary outcomes

1

Description
Changes in serum IgG levels in the second week compared to the before of the intervention
Timepoint
Before intervention and the second week after intervention
Method of measurement
ELISA serum IgG level measurement kit

2

Description
Changes in serum IgG levels in the fourth week compared to the before of intervention
Timepoint
Before intervention and the fourth week after intervention
Method of measurement
ELISA serum IgG level measurement kit

3

Description
Changes in liver function tests in the fourth week compared to the before of intervention
Timepoint
Before intervention and the fourth week after intervention
Method of measurement
Aspartate aminotransferase, Alanine aminotransferase, Alkaline phosphatase and Bilirubin levels measurment kits

4

Description
Changes in renal tests in the fourth week compared to the before of intervention
Timepoint
Before intervention and the fourth week after intervention
Method of measurement
Blood Urea Nitrogen and Creatinine levels measurement kits

5

Description
Changes in blood cell count in the fourth week compared to the before of intervention
Timepoint
Before intervention and the fourth week after intervention
Method of measurement
Automated hematology analyzer

6

Description
Changes in inflammatory factors in the fourth week compared to the before of intervention
Timepoint
Before intervention and the fourth week after intervention
Method of measurement
Westergren method for Erythrocyte Sedimentation Rate, ELISA kit for C-reactive protein measurement

7

Description
Incidence and severity of acute bacterial infections
Timepoint
During the study
Method of measurement
Microscopic observation (Gram staining), phenotypic study of bacterial properties based on cell culture media, detection of antibodies against bacterial structures with the serological methods

8

Description
The rate of possible adverse reactions
Timepoint
During the study
Method of measurement
Clinical examination and patient history

9

Description
The incidence of death during the study
Timepoint
During the study
Method of measurement
Clinical examination

Intervention groups

1

Description
Intravenous infusion of human polyclonal antibody (IVIg) produced by MedVac BioPharma Company at a dose of 600 milligram per kilogram of body weight in a single dose
Category

Treatment - Drugs

2

Description
Intravenous infusion of human polyclonal antibody (IVIg) produced by Biotest Company at a dose of 600 milligram per kilogram of body weight in a single dose
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Mofid Children Hospital, Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr. Peyman Eshghi
Street address
Shariati Street
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Tehran
Province
Tehran
Postal code
1546815514
Phone
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Email
p_eshghi@sbmu.ac.ir

2

Recruitment center
Name of recruitment center
Rasool Akram Hospital, Iran University of Medical Sciences
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Medvac BioPharma Company
Full name of responsible person
Dr. Bardia Farzamfar
Street address
Phase 2 of the intersection of Golestan 9th and Mahestan St, Baharestan Industrial Town,5 km of Karaj-Qazvin Hwy
City
Karaj
Province
Alborz
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3197994599
Phone
+98 26 3476 0942
Email
info@medvac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Medvac BioPharma 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
Tehran University of Medical Sciences
Full name of responsible person
Dr. Gita Shafiee
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Epidemiology
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No. 10, Jalal Al-e-Ahmad St., Chamran Hwy
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Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

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Position
Professor

Latest degree
Subspecialist

Other areas of specialty/work
Hematology

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Person responsible for updating data

Contact

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Full name of responsible person
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Assistant Professor

Latest degree
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Other areas of specialty/work
Epidemiology

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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
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
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
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
After completion of the study, submission of the final report to the Ministry of Health and scientific article release, all unidentifiable patient data will be shared.

When the data will become available and for how long
After publishing a scientific article and for 5 years

To whom data/document is available
Researchers in the field of medicine and health

Under which criteria data/document could be used
By submitting a scientific proposal, approval of the ethics committee and after the written consent of MedVac BioPharma Company

From where data/document is obtainable
Principle investigators of the trial

What processes are involved for a request to access data/document
1- Submitting a written request including the title of the research and the required variables along with the scientific proposal to one of the principle investigators and obtaining his written consent 2- Obtaining the written consent of MedVac BioPharma Company 3- Obtaining the approval of the ethics committee

Comments