

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Determination of specific antibody titre against Pneumococcus and its relation with recurrent infection in patients with ataxia-telangiectasia and IgA deficiency

Protocol summary

Study aim

- Determination of specific antibodies titre against pneumococcus in patients - Comparison of clinical manifestations and immunological data in patients with or without defect in specific antibodies production against pneumococcus

Design

Without control group

Settings and conduct

1. Select of patients diagnosed with selective IgA deficiency and ataxia-telangiectasia based on defined criteria 2. Completing questionnaire containing demographic, clinical manifestations and immunological data Method: 1. We will obtain a sample of 10-5 ml of blood sample of selected patients 2- A 0.5-milliliter dose of non-conjunctiva pneumococcal polyvalent vaccine (PNEUMO 23® Aventis, Pasteur, France) will inject in all patients. 3- Three weeks after pneumococcal vaccination, we will take 10-5 ml of blood of selected patients 4- specific antibody titre against pneumococcal will measure before and after vaccination by ELISA method 5- According to the specific antibody response to pneumococci, the patients will be classified into two groups and their relationship with the presence or absence of specific antibody response against pneumococci in patients with recurrent infections will be evaluated.

Participants/Inclusion and exclusion criteria

Patients diagnosed with selective IgA deficiency and ataxia-telangiectasia based on defined criteria

Intervention groups

All patients receive a 0.5-milliliter dose of non-conjunctiva pneumococcal polyvalent vaccine (PNEUMO 23® Aventis, Pasteur, France).

Main outcome variables

Defect in production of specific antibodies titre against pneumococcus in patients with ataxia-telangiectasia and

selective IgA deficiency could be related to manifestation of recurrent infections

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190508043517N1**

Registration date: **2019-06-17, 1398/03/27**

Registration timing: **registered_while_recruiting**

Last update: **2019-06-17, 1398/03/27**

Update count: **0**

Registration date

2019-06-17, 1398/03/27

Registrant information

Name

asghar aghamohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6612 9187

Email address

aghamohammadi@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-08, 1398/02/18

Expected recruitment end date

2019-12-09, 1398/09/18

Actual recruitment start date

empty

Actual recruitment end date

empty
Trial completion date
empty

Scientific title
Determination of specific antibody titre against
Pneumococcus and its relation with recurrent infection in
patients with ataxia-telangiectasia and IgA deficiency

Public title
Evaluation of specific antibody titre against
Pneumococcus in patients with Ataxia-telangiectasia and
IgA deficiency

Purpose
Health service research

Inclusion/Exclusion criteria
Inclusion criteria:
Patients diagnosed with selective IgA deficiency and
ataxia-telangiectasia based on defined criteria

Exclusion criteria:

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **100**

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
Tehran University of Medical Sciences
Street address
Nosrat
City
Tehran
Province
Tehran
Postal code
1419853773
Approval date

2019-05-04, 1398/02/14
Ethics committee reference number
IR.TUMS.CHMC.REC.1398.020

Health conditions studied

1
Description of health condition studied
Ataxia-telangiectasia
ICD-10 code
G11.3
ICD-10 code description
Cerebellar ataxia with defective DNA repair

2
Description of health condition studied
IgA deficiency
ICD-10 code
D80.2
ICD-10 code description
Selective deficiency of immunoglobulin A [IgA]

Primary outcomes

1
Description
Ataxia-telangiectasia
Timepoint
Before intervention
Method of measurement
According to the ESID diagnostic criteria

2
Description
IgA deficiency
Timepoint
Before intervention
Method of measurement
According to the ESID diagnostic criteria

3
Description
Sex
Timepoint
Before intervention
Method of measurement
Questionnaire

4
Description
Age
Timepoint
Before intervention
Method of measurement
Questionnaire

Secondary outcomes

1

Description

Determination of the pneumococcus specific antibodies level

Timepoint

Before and after intervention

Method of measurement

ELISA

Intervention groups

1

Description

One-half-milliliter dose of non-conjugate pneumococcal polyvalent vaccine (PNEUMO 23® Aventis, Pasteur, France)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Research center for immunodeficiency diseases

Full name of responsible person

Asghar Aghamohammadi

Street address

Nosrat

City

Tehran

Province

Tehran

Postal code

1419853773

Phone

+98 21 6612 9187

Email

aghamohammadi@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad ali Sahraeiyan

Street address

Ghods

City

Tehran

Province

Tehran

Postal code

1415944911

Phone

+98 21 8898 7381

Email

mohammadalisahraeiyan@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

100

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

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mahsa Sohani

Position

Master of Science (MSc)

Latest degree

Master

Other areas of specialty/work

Hematology

Street address

Nosrat

City

Tehran

Province

Tehran

Postal code

1419853773

Phone

+98 21 6612 9187

Email

sohanimahsa1369@gmail.com

Person responsible for scientific inquiries

Contact

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Tehran University of Medical Sciences

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Master of Science (MSc)

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1419853773

Phone

+98 21 6612 9187

Email

sohanimahsa1369@gmail.com

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Phone

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Email

sohanimahsa1369@gmail.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

Person responsible for updating data**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Mahsa Sohani

Position

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Latest degree

Master

Other areas of specialty/work

Hematology

Street address

Nosrat

City

Tehran