

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

Antibody Response to Pneumococcal Vaccines, Polysaccharides 23 Valence (PPV) and Conjugates 7 Valence (PCV) in Beta Thalassemia Major without Spleen

Protocol summary

Summary

The aim of this study is comparing the effect of PPV and PCV vaccines in splenectomized thalassemia major at thalassemia research center of Mazandaran University of medical sciences. Inclusion Criteria: All of Splenectomized Thalassemia Major Patients who have not received Pneumococcal Vaccine or have received it more than 5 years ago. Exclusions Criteria: Tthalassemia Major with Spleen. The outcome of this study is antibody response to pneumococcal vaccine of PPV or PCV. Before and after vaccination, blood samples are taken to check the level of pneumococcal antibodies.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201110116660N3**

Registration date: **2011-11-20, 1390/08/29**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-11-20, 1390/08/29

Registrant information

Name

Javad Ghafari

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 3326 0054

Email address

ghafari@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Sciences

Expected recruitment start date

2011-07-27, 1390/05/05

Expected recruitment end date

2012-07-26, 1391/05/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Antibody Response to Pneumococcal Vaccines, Polysaccharides 23 Valence (PPV) and Conjugates 7 Valence (PCV) in Beta Thalassemia Major without Spleen

Public title

Antibody Response to Pneumococcal Vaccines PPV and PCV in Beta Thalassemia Major without Spleen

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria: Splenectomized Thalassemia Major Patients who have not received Pneumococcal Vaccine or have received it more than 5 years ago. Exclusions Criteria: Tthalassemia Major with Spleen.

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 50

Randomization (investigator's opinion)

Randomized

Randomization description**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**

Mazandaran University of Medical Sciences

Street address

NO.2 Building, Mazandaran University of Medical Sciences, Moallem Square

City

Sari

Postal code**Approval date**

2011-08-03, 1390/05/12

Ethics committee reference number

80-90

Health conditions studied**1****Description of health condition studied**

Beta Thalassemia Major

ICD-10 code

D56.1

ICD-10 code description

Beta thalassaemia

Primary outcomes**1****Description**

Antibody response to pneumococcal vaccines ppv

Timepoint

Evaluation of IgG eight weeks after vaccination

Method of measurement

Laboratory Test

2**Description**

Antibody response to pneumococcal vaccines pcv

Timepoint

Evaluation of IgG three months after vaccination

Method of measurement

Laboratory Test

Secondary outcomes**1****Description**

Along Diseases

Timepoint

After of study

Method of measurement

Laboratory Test

Intervention groups**1****Description**

PPV vaccine, once, 0.5 cc

Category

Prevention

2**Description**

PCV vaccine, once, 0.5 cc

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

Thalassemia Clinic, Boali Hospital

Full name of responsible person

Dr Javad Ghafari

Street address

Boali Hospital, P1asdaran blvd, Emam square

City

Sari

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

Dr Ahmadali Enayati

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No.2 Building of Mazandaran University of Medical Sciences, Moaalem Square

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Grant name

-
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source
Mazandaran University of Medical Sciences

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
Mazandaran University of Medical Sciences

Full name of responsible person
Dr Javad Ghafari

Position
Alergist and Clinical Immounologist, Associate of Professor

Other areas of specialty/work

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Web page address

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