

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

Evaluation of response to hepatitis B vaccine in Autistic child in comparison with control group

Protocol summary

Study aim

HBs-Ab titer Determining in Autistic child and immunological memory assessment by booster injection, as well as evaluation of viral factors in cases of non-responsiveness to hepatitis B vaccine in comparison with control. persistence of anti-HBs antibody determination between autistic and healthy children after primary vaccination achievement . Determination of non-responsiveness rate to hepatitis B vaccine in Autistic child in comparison with control after full vaccination.

Design

An intervention, descriptive and prospective study and clinical trial has been conducted on autistic children with healthy children as control and outcome assessment.

Settings and conduct

Experiments are carried out at Hepatitis B Laboratory of Virology Department of School of Public Health, Tehran University of Medical Sciences

Participants/Inclusion and exclusion criteria

To included in the study in ASD group The child have Proven autism, parental consent for their child's participation. No Sickness and no fever. to included in the study in control group, The child be healthy and have parental consent. for excluding from study Every time parents abandon cooperation The child has an antibody level higher than 10 mIU/mL or reaches the antibody titer higher than 10 mIU/ml after vaccine injection.

Intervention groups

Hepatitis B vaccine will be injected to Autistic child and healthy controls whom have antibody titre less than 10 mIU/mL

Main outcome variables

The responsiveness rate for the hepatitis B vaccine will be determined in children with autism. Antibody durability and prevalence of hepatitis B virus seromarkers will be determined in both groups. The immunological memory status against HBV vaccine will be disclosed.

General information

Reason for update

Acronym

ASD

IRCT registration information

IRCT registration number: **IRCT20130904014562N2**

Registration date: **2018-04-18, 1397/01/29**

Registration timing: **retrospective**

Last update: **2018-04-18, 1397/01/29**

Update count: **0**

Registration date

2018-04-18, 1397/01/29

Registrant information

Name

Seyed Mohammad Jazayeri

Name of organization / entity

Hepatitis B Lab-Dept Virology

Country

Iran (Islamic Republic of)

Phone

+98 21 8899 2660

Email address

jazayerism@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-02-19, 1395/12/01

Expected recruitment end date

2017-09-21, 1396/06/30

Actual recruitment start date

2017-02-19, 1395/12/01

Actual recruitment end date

2017-09-21, 1396/06/30

Trial completion date

empty

Scientific title

Evaluation of response to hepatitis B vaccine in Autistic child in comparison with control group

Public title

Responsiveness to the hepatitis B vaccine in Autistic child

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Presence of autism in the child Maximum age 15 years
Parental consent regarding the participation of their child in phlebotomy and vaccine injection

Exclusion criteria:

Parental dissatisfaction HBs-Ab titer Existence or increase above 10 mIU/mL

Age

To 15 years old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 105

Actual sample size reached: 105

Randomization (investigator's opinion)

N/A

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

Ethics committee of Tehran University of Medical Sciences

Street address

Hepatitis B Lab-Department Virology, School of Public Health, Tehran University of Medical Sciences, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

14155-6446

Approval date

2016-07-03, 1395/04/13

Ethics committee reference number

IR.TUMS.REC 139502754

Health conditions studied

1

Description of health condition studied

Autism

ICD-10 code

F84.0

ICD-10 code description

Childhood autism

Primary outcomes

1

Description

The variable in the study is the HBs-Ab titre. By Booster injection HBs-Ab titer will be increased and marked by ELISA

Timepoint

Evaluation time is before vaccine administration and one month after vaccine injection

Method of measurement

ELISA method employed

Secondary outcomes

empty

Intervention groups

1

Description

In the control group, children who have HBs-Ab titer less than 10 mIU/mL receive hepatitis B vaccine.

Category

Prevention

2

Description

In the ASD group, children who have HBs-Ab titer less than 10 mIU/mL receive hepatitis B vaccine.:

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Behara Rehabilitation Center, Shahid Beheshti University

Full name of responsible person

Haleh Ofoghi

Street address

Family Research Institute, in front of the Faculty of Literature, Shahid Beheshti University, Evin, Tehran

City

Tehran

Province

Tehran

Postal code

1983963113

Phone

+98 21 2990 5430

Fax

+98 21 2990 2368

Email

halehofoghi@yahoo.com

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

Tehran University of Medical Sciences

Full name of responsible person

Seyed Mohammad jazayeri

Street address

Hepatitis B Lab-Department Virology, School of Public Health, Tehran University of Medical Sciences, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

15155-6446

Phone

+98 21 8899 2660

Fax

+98 21 8899 2660

Email

jazayerism@tums.ac.ir

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

Seyed mohammad Jazayeri

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Virology

Street address

Hepatitis B Lab-Department Virology, School of Public Health, Tehran University of Medical Sciences, Tehran, Iran

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Province

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Fax

+98 21 8899 2660

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Seyed Mohammad Jazayeri

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+98 21 8899 2660

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Person responsible for updating data

Contact

Name of organization / entity

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Fax

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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

Not applicable

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The total data can be shared after unidentifiable people

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

All people who are willing to work in this field

Under which criteria data/document could be used

Purely scientific research

From where data/document is obtainable

Hepatitis B Lab-Department Virology, School of Public Health, Tehran University of Medical Sciences, Tehran, Iran

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

Send request type by email Confirm and validate email Reply to the email and send the documentation

Comments