Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 compassion 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 compression 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 statues 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
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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
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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
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
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Hepatitis B Lab-Department Virology, School of Public Health, Tehran University of Medical Sciences, Tehran, Iran
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Person responsible for updating data

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Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Virology

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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