Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jul 2026

Study for Safety , immunogenicity and efficacy of intramuscular administration of Haemophilus Influenzae type b conjugate vaccine manufactured by Masoondarou Co. (MAS-HibVAC®) in 50 children and compare with foreign sample

Protocol summary

Summary

The annual incidence of bacterimia and meningitis caused by Haemophilus influenzae type b (Hib) among the children in the firs 5 years of life is in the range 0.02 – 0.5 % with mortality of 5 – 10 % . Hib polysaccharide conjugate vaccines showed to be a effective means of protecting against such infections . The objective of the study is evaluate safety , immunogenicity and efficacy of intramuscular administration of Hib conjugate vaccine manufactured by Masoondarou Co. (MAS-HibVAC®) in 50 children and compare with foreign sample . Trial design : The trial is a bridging study , Double-blind , multicentric Comparator-controlled , Randomized . A -Trial Volunteers : - Primary inclusion criteria to the trial : Male or females age 2-4 months , good Health , informed consent by the legal guardians , No Known immunological deficiency , No known serious diseases, No involvement in other drug or vaccine clinical trials , No known allergy to biological products . - Primary Exclusion criteria to the trial : Need for use of special drugs during of the trial , Withdrawal of consent by the legal guardians , evidence of any unusual condition in volunteer , evidence of any serious diseases and abnormal results of paraclinical tests . - Sample size : 50 volunteers will be enrolled in the study and each of the volunteers monitored for a maximum 6 months . B- Interventions : Interment 1 is Hib polysaccharide – tetanus toxoid conjugate vaccine manufactured by MASOONDAROU Co. (MAS-HibVAC®) and interment 2 Hib polysaccharide – tetanus toxoid conjugate vaccine manufactured by Sanofipasteur Co. (ActHib®) each with dose of 0.5 milliliter . C- Intervention time : Volunteers will be vaccinated by 2 dose of vaccines intramuscularly with 2 months interval . D- Trial Endpoints : Primary endpoints includes occurrence any local and systemic adverse effects , Hib anticapsular antibody titer in serum of children before and after vaccination , efficacy of vaccines and secondary endpoints effects of vaccines on the functions of blood , hepatic , renal , nervous , cardiac and respiratory systems .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201008084536N1**
Registration date: **2012-03-05, 1390/12/15**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2012-03-05, 1390/12/15

Registrant information

Name

Naser Mohammadpour

Name of organization / entity

Masoon Darou Biopharmaceutical Co.

Country

Iran (Islamic Republic of)

Phone

+98 26 1667 0349

Email address

info@masoondarou.net

Recruitment status

Recruitment complete

Funding source

MASOONDAROU BIOPHARMACEUTICAL Co.

Expected recruitment start date

2012-04-20, 1391/02/01

Expected recruitment end date

2012-06-21, 1391/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study for Safety , immunogenicity and efficacy of intramuscular administration of Haemophilus Influenzae type b conjugate vaccine manufactured by Masoondarou Co. (MAS-HibVAC®) in 50 children and compare with foreign sample

Public title

Study for effects of Haemophilus Influenzae type b conjugate vaccine in children

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria : 1-Male or females age 2-4 months. 2-Generally in good Health . 3- Written informed consent by the legal guardians. 4- No Known immunological deficiency, including HIV infection . 5- No known serious diseases, including diabetes , and epilepsy . 6- No involvement in other drug or vaccine clinical trials during the study period . 7- No current or foreseeable use of immunosupressors within 1 month prior to vaccination and during the period of study . 8- No known allergy to biological products . 9- No history of vaccination against Haemophilus Influenzae type b . 10- No fever at the time of vaccination (oral body temperature > 37.5 Ċ) . 11- No known allergy to a vaccine component. Exclusion criteria : 1- Need for use of special drugs (immunosupressores ,.....) during of the trial . 2- Withdrawal of consent by the legal guardians . 3- Evidence of any unusual condition in volunteer on the basis of trial medical team idea (serious diseases , surgery , ...) . 4- Evidence of any serious diseases , including diabetes , and epilepsy . 5- Abnormal results of hematology and biochemistry tests such as lococytopenia , lococytosis , thrombocytopenia , anemia , hypercalemia , hypocalemia , hypernatremia , hyponatremia ,.....

Age

From **1 year** old to **1 year** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Deputy of Shahid Beheshti Medical Univercity

Street address

Shahid Beheshti Medical Univercity, Shahid Chamran Exp. Way (Evin) .

City

Tehran

Postal code

Approval date

2012-02-18, 1390/11/29

Ethics committee reference number

400/9172

Health conditions studied

1

Description of health condition studied

Children Haemophilus Meningitis

ICD-10 code

G00.0

ICD-10 code description

Meningitis due to Haemophilus influenzae

Primary outcomes

1

Description

Occurrence any local and systemic adverse effects

Timepoint

8th, 16th and 20th weeks

Method of measurement

Paraclinical assesment, clinical examination and Diary card reports

2

Description

Immunogenicity

Timepoint

At the Day 30 after the end of injection

Method of measurement

Elisa

3

Description
Efficacy
Timepoint
At Day 30 after the end of injection
Method of measurement
Bactricidal effect of serum of volunteers

Secondary outcomes

1

Description
Effects of vaccines on the functions of blood system
Timepoint
Before vaccine administration and 30 days after end vaccine injection
Method of measurement
Paraclinical tests

2

Description
Effects of vaccines on the functions of hepatic and renal system
Timepoint
Before vaccine administration and 30 days after end vaccine injection
Method of measurement
Paraclinical tests

3

Description
Effects of vaccines on the functions of nervous system
Timepoint
All of study duration
Method of measurement
Clinical examination

4

Description
Effects of vaccines on the functions of cardiac and respiratory systems .
Timepoint
All of study duration
Method of measurement
Clinical examination

Intervention groups

1

Description
interment 2 Hib polysaccharide – tetanus toxoid conjugate vaccine manufactured by Novartis
Category
Prevention

2

Description
Interment 1 is Hib polysaccharide – tetanus toxoid conjugate vaccine manufactured by MASOONDAROU Co. (MAS-HibVAC®)
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Loghman Hospital
Full name of responsible person
Dr Parviz Vahdani
Street address
Hor Square , Kamali Street
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Masoondarou Co.
Full name of responsible person
Bayat Marzieh
Street address
Simindasht Industrial City
City
Karaj
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Masoondarou Co.
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
Masoondarou Co.
Full name of responsible person
Zolfagharian H

Position
Doctor
Other areas of specialty/work
Street address
Simindasht Industrial City
City
Karaj
Postal code
Phone
+98 26 1667 0350
Fax
+98 26 1667 0349
Email
zolfagharianh@yahoo.com
Web page address
http://www.masoondarou.net

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Science
Full name of responsible person
Sanaie Anahita
Position
Assistant Professor
Other areas of specialty/work
Street address
Hore Square , Kamali Street
City
tehran
Postal code
Phone
+98 21 5541 9007
Fax
+98 21 5541 9007
Email
anahita_sam@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Masoondarou Co.
Full name of responsible person
Mohammadpour Naser
Position
Doctor
Other areas of specialty/work
Street address
Simindasht Industrial City
City
Karaj
Postal code
Phone
+98 26 1667 0350
Fax
+98 26 1667 0349
Email
info@www.masoondarou.net
Web page address
http://www.masoondarou.net

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