

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 bacteremia and meningitis caused by Haemophilus influenzae type b (Hib) among the children in the first 5 years of life is in the range 0.02 – 0.5 % with mortality of 5 – 10 % . Hib polysaccharide conjugate vaccines showed to be an 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 : Intervention 1 is Hib polysaccharide – tetanus toxoid conjugate vaccine manufactured by MASOONDAROU Co. (MAS-HibVAC®) and intervention 2 Hib polysaccharide – tetanus toxoid conjugate vaccine manufactured by Sanofi Pasteur 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 immunosuppressors 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 °C) . 11- No known allergy to a vaccine component. Exclusion criteria : 1- Need for use of special drugs (immunosuppressores ,.....) 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 leucocytopenia , leucocytosis , thrombocytopenia , anemia , hypercalcemia , hypocalcemia , 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 University

Street address

Shahid Beheshti Medical University, 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