Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Clinical trial of evaluation of 18th month of age vaccines injection order (intramuscular first and then subcutaneous or subcutaneous first and then intramuscular) on pain of intramuscular injection of diphtheria, pertussis and tetanus vaccine

Protocol summary

Summary

This clinical trial will be done to answer this question that whether intramuscular injection of diphtheria, pertussis and tetanus (DPT) vaccine first and then subcutaneous injection of measles, mumps and rubella (MMR) vaccine or subcutaneous injection of MMR vaccine first and then intramuscular injection of DPT vaccine, can cause less pain of DPT vaccine intramuscular injection. In a clinical trial, sixty healthy 18 month old children who will be referred for vaccination to Primary Health Care Center of Akbari in Yazd, Iran will be randomly distributed into two groups. In group I, intramuscular DPT vaccine will be injected first and then subcutaneous injection of MMR will be done and in group II, children will receive subcutaneous injection of MMR vaccine first and then intramuscular injection of DPT vaccine. In all of them, vaccines will be injected in similar conditions and by a trained person. Primary outcomes include pain score during DPT vaccine injection, pain score during MMR vaccine injection and obtaining of pain score of less than four during DPT vaccine injection. Pain score when the needle is inserted to the skin will be assessed based on Modified Behavioral Pain Scale. Secondary outcome will be duration of baby crying during DPT vaccine injection.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201409042639N14**
Registration date: **2014-10-10, 1393/07/18**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-10-10, 1393/07/18

Registrant information

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Razieh Fallah
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Recruitment status

Recruitment complete

Funding source

Research Deputy of Shahid Sadoughi University of Medical Sciences , Yazd, Iran

Expected recruitment start date

2014-08-26, 1393/06/04

Expected recruitment end date

2015-02-20, 1393/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of evaluation of 18th month of age vaccines injection order (intramuscular first and then subcutaneous or subcutaneous first and then intramuscular) on pain of intramuscular injection of diphtheria, pertussis and tetanus vaccine

Public title
Effect of the order of injecting 18th month of age vaccines on pain
Purpose
Other
Inclusion/Exclusion criteria
Inclusion criteria: 18 months of age, being in a healthy medical condition and referring for vaccination to primary health care center Exclusion criteria: neurodevelopmental delay, severe congenital malformation and receiving sedative hypnotic drugs within the past 24 hours
Age
From **1 year** old to **1 year** old
Gender
Both

Phase
1
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
The children in this trial will be randomized by random numbers table.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Sadoughi University of Medical Sciences, Yazd, Iran
Street address
central building of university, Bahonar square
City
Yazd
Postal code
Approval date
2014-08-24, 1393/06/02
Ethics committee reference number
17/1/107183/پ

Health conditions studied

1

Description of health condition studied
vaccination
ICD-10 code
Z27
ICD-10 code description
Need for immunization against combinations of infectious diseases

Primary outcomes

1

Description
pain score during diphtheria, pertussis and tetanus (DPT) vaccine injection
Timepoint
time of needle insertion to skin
Method of measurement
Modified Behavioral Pain Scale table

2

Description
pain score during measles, mumps and rubella (MMR) vaccine injection
Timepoint
time of measles, mumps and rubella (MMR) vaccine injection
Method of measurement
Modified Behavioral Pain Scale table

3

Description
obtaining of pain score of less than four during diphtheria, pertussis and tetanus (DPT) vaccine injection
Timepoint
time of diphtheria, pertussis and tetanus (DPT) vaccine injection
Method of measurement
Modified Behavioral Pain Scale table

Secondary outcomes

1

Description
duration of baby crying after injection of DPT vaccine
Timepoint
every 10 seconds after vaccine injection until stopping of crying
Method of measurement
by chronometer

Intervention groups

1

Description
intramuscular injection of a single dose of DPT

(diphtheria, pertussis and tetanus) vaccine and then subcutaneous injection of a single dose of combination of measles, mumps and rubella vaccines

Category
Prevention

2

Description
subcutaneous injection of a single dose of combination of measles, mumps and rubella vaccines and then intramuscular injection of a single dose of DPT (diphtheria, pertussis and tetanus) vaccine

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Primary Health Care Center of Akbari

Full name of responsible person
Dr.Hossein Gholami

Street address
Timsar Fallahi Street , Emam Hassan square,Safaeeh,Yazd, Iran

City
Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Research Deputy of Shahid Sadoughi University of Medical Sciences , Yazd, Iran

Full name of responsible person
Dr.Fatemah Ezoddini

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central building of university , Bahonar 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
Research Deputy of Shahid Sadoughi University of Medical Sciences , Yazd, Iran

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
Shahid Sadoughi University of Medical Sciences , Yazd , Iran

Full name of responsible person
Dr. Hosein Gholami

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Pediatric resident

Other areas of specialty/work

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Pediatric Neurologist , Associate professor

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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