

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

The effect of shotblocker on vaccination pain among infants

Protocol summary

Study aim

The effect of shot blocker on vaccine pain in infants

Design

In this study, 80 cases of 6-month-old infants referred to Birjand Mehrshahr Comprehensive Health Services Center were selected by convenience sampling method and randomly assigned into two groups of block shot and control group.

Settings and conduct

In this single-blind study, the research setting will be Mehrshahr Integrated Health Services Research Center in Birjand. There is a test group and a control group. In addition to the participants who are unaware of their allocations, two individuals who are not aware of the objectives of the project will check the videos and review the variables of the study after the sampling is completed.

Participants/Inclusion and exclusion criteria

Main inclusion criteria: six-month-old children; guardian consent for participation in the study; referral to receive the pentavalent vaccine; and term baby at birth (37-42 weeks). Main exclusion criteria: Consumption of analgesics by the child and mother during 48 hours before intervention; history of injections other than post-birth vaccine and screening tests.

Intervention groups

The test group will use a blocker shot 20 seconds before injection until the end of the vaccine injection. And in the control group there will be no intervention and they will be vaccinated according to the routine of the center. The modified behavioral pain scale (flacc) and cry time will be used to assess pain scores 15 seconds after immunization.

Main outcome variables

Pain severity; crying duration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191128045534N1**

Registration date: **2020-04-22, 1399/02/03**

Registration timing: **retrospective**

Last update: **2020-04-22, 1399/02/03**

Update count: **0**

Registration date

2020-04-22, 1399/02/03

Registrant information

Name

ghazal afshari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 56 3239 5000

Email address

ghazalafshari505@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-04, 1398/09/13

Expected recruitment end date

2020-03-03, 1398/12/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of shotblocker on vaccination pain among infants

Public title

The Effect of Blocker on Infant Pain

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Qualify for a fivefold vaccine birth is term (37-42) Child's growth curve is normal the child is quiet and without crying Infant diaper is dry

Exclusion criteria:

Consumption of analgesics by the child and mother during 48 hours before intervention history of injections other than post-birth vaccine and screening tests history of surgery and hospitalization Cerebral palsy Mental retardation Acute or chronic illness

Age

From **6 months** old to **6 months** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

he allocation is via random blocks such that in each block, there will be two individuals. The first person will choose one of the two envelopes and will be placed in one of the two groups, and the other one will then be drawn into the other one groups by the same token

Blinding (investigator's opinion)

Single blinded

Blinding description

What is meant to be omitted from a single blind is that the researcher's assistant, the person reviewing the film to assess pain scores, is unaware of the aims and assumptions of the research, but that complete blinding is not possible, and that the aim was even with these measures. Reduce bias whenever possible

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

ghazalafshari

Street address

Central Organization of Birjand University of Medical Sciences, Khorasan, Birjand, Ghafari Street

City

birjand

Province

South Khorasan

Postal code

۳۲۳۹۵۰۰۰

Approval date

2019-12-04, 1398/09/13

Ethics committee reference number

IR.BUMS.REC.1398.238

Health conditions studied

1

Description of health condition studied

Vaccine pain in infants

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

pain

Timepoint

20seconds befor vaccination Until the end of the injection

Method of measurement

flacc scale

2

Description

cry time

Timepoint

injection until the end of time crying

Method of measurement

cronometr

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The test group will use a shotblocker 20 seconds before the end of the vaccine injection.

Category

Other

2

Description

Control group: Control group will receive standard care in health centers.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Mehrshahr Health Center

Full name of responsible person

ghazalafshari

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Birjand - Mehrshahr - Imam Ali Street - Corner of Imam Ali 4

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

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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

Birjand 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

Birjand University of Medical Sciences

Full name of responsible person

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Position

student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for updating data

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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

Yes - There is a plan to make this available

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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Deidentified Individual Participant Data Set

When the data will become available and for how long

When the extracted paper is published and for 6 months

To whom data/document is available

for researchers

Under which criteria data/document could be used

research purposes

From where data/document is obtainable

personal correspondence with the corresponding author

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

email

Comments