

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

Comparison of the effect of immunization education by two methods of lecture and movie to parents on delay of vaccination in children under 12 months

Protocol summary

Study aim

Determining the effect of immunization education by two methods of lecture and movie to parents on delay of vaccination in children under 12 months

Design

A quasi-experimental intervention study with two intervention groups with parallel groups, without blinding, randomized, on 366 samples. For randomization, a simple random method of coin tossing is used.

Settings and conduct

Two centers and four health centers in Shushtar city of Khuzestan province, research samples of Iranian parents and foreign immigrants with eligible children under 12 months, one center and two centers as intervention group 1, another intervention group 2, sampling with daily presence of the researcher in Study areas, intervention in small groups of 5 to 8 people (in both groups) and in accordance with health protocols, with a duration of 15 to 20 minutes, the interval between training sessions and the expected time for vaccination in the range of 15 to 60 days.

Participants/Inclusion and exclusion criteria

Fluency in Persian and at least 7 days delay in injecting one or more vaccines under one year are entry requirements; existence of any problems or diseases that interfere with the vaccination process; lack of vaccination history and no vaccination card; multiple pregnancies; premature birth; less than 15 days and more than 60 days between vaccination training and vaccination, are non-entry.

Intervention groups

Intervention group 1: in this group, education of children vaccination is given to parents by lecture method.
Intervention group 2: in this group, education of children vaccination is given to parents based on educational video based on Meyer multimedia principles and in the

form of image, audio file with image (podcast) and video in MPEG-4 (MP4) format, teaches parents.

Main outcome variables

If any of the training methods are effective, it can be used in other similar areas.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180427039436N8**

Registration date: **2020-11-03, 1399/08/13**

Registration timing: **prospective**

Last update: **2020-11-03, 1399/08/13**

Update count: **0**

Registration date

2020-11-03, 1399/08/13

Registrant information

Name

Leila Amiri Farahani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-05, 1399/09/15

Expected recruitment end date

2020-12-20, 1399/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of immunization education by two methods of lecture and movie to parents on delay of vaccination in children under 12 months

Public title

Immunization education to parents with children under one year old

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Fluency in Persian At least 7 days delay in injecting one or more vaccines under one year

Exclusion criteria:

Any problems or illnesses that interfere with the vaccine injection process, such as: medical prohibition on injection, high fever, seizures, or severe allergic reaction. Uncertainty of vaccination history based on information registered in the sib system and no vaccine card Twin pregnancy Preterm birth Less than 15 days and more than 60 days between vaccination education and vaccine injection

Age

From **12 months** old to **24 months** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **366**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, at first, with a simple random coin toss method, one of the centers is considered as intervention group 1 (film vaccination training) and the other center is considered as intervention group 2 (lecture vaccination training) and Of the four bases in the same way, two bases are in group 1 and the other two bases are in group 2

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 Iran University of Medical Sciences

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Next to Milad Tower, Hemmat Highway

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1996713883

Approval date

2020-10-13, 1399/07/22

Ethics committee reference number

IR.IUMS.REC.1399.646

Health conditions studied**1****Description of health condition studied**

Vaccination education in two ways: lectures and videos

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Determining the frequency of delay in vaccination of children after intervention in the educational group by film method

Timepoint

The nearest vaccine injection after an educational intervention

Method of measurement

Child vaccine card, vaccine registration booklet, Ministry of Health Sib system

2**Description**

Determining the frequency of delay in vaccination of children after intervention in the educational group by lecturing method

Timepoint

The nearest vaccine injection after an educational intervention

Method of measurement

Child vaccine card, vaccine registration booklet, Ministry of Health Sib system

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: The first intervention (vaccination training by video method) Training the content of the intervention in the form of 15-20 minute educational video based on Meyer multimedia principles and in the form of image, audio file with image (podcast) and video in MPEG format 4. (MP4), in small groups of 5 to 8 people and will be done in accordance with health protocols and social distance

Category

N/A

2

Description

Intervention group: The second intervention (lecture training) is designed as a training session with a duration of 15-20 minutes for eligible parents in the form of lectures and in small groups of 5 to 8 people and in accordance with the protocol Health and social distancing will be done

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Urban Health Center No. 3

Full name of responsible person

Azam songol

Street address

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Recruitment center

Name of recruitment center

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Full name of responsible person

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3

Recruitment center

Name of recruitment center

Health Base No. 2, Health Center 3

Full name of responsible person

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Recruitment center

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Name of recruitment center

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Sponsors / Funding sources

1

Sponsor

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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

Iran 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
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Full name of responsible person
Leila Amiri Farahani
Position
Associate professor
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available