Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 Oct 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)

Phone

+98 21 4365 1139

Email address

l.amirifarahani@gmail.com

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
Street address
Next to Milad Tower, Hemmat Highway
City
Tehran
Province
Tehran
Postal code
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
Fakharyan Square, Darvaze
City
Shushtar
Province
Khouzestan
Postal code
8453464516
Phone
+98 61 3624 0160
Email
azamsongol@yahoo.com

2

Recruitment center
Name of recruitment center
Al ghafor Health Center
Full name of responsible person
Azam Songol
Street address
Golzar Shohada Ave, Jade Sahebzaman
City
Shushtar
Province
Khouzestan
Postal code
8453464516
Phone
+98 61 3624 0160
Email
azamsongol@yahoo.com

3

Recruitment center
Name of recruitment center
Health Base No. 2, Health Center 3
Full name of responsible person
Azam Songol
Street address
Shahid Jamshidi Alley, Jade Sahebzaman
City
Shushtar
Province
Khouzestan
Postal code
8453464516
Phone
+98 61 3624 0160
Email
azamsongol@yahoo.com

4

Recruitment center
Name of recruitment center
Health Base No. 1, Health Center 3
Full name of responsible person
Azam Songol
Street address
Khezre Nabi Ave, Darvaze
City
Shushtar
Province
Khouzestan
Postal code
8453464516
Phone
+98 61 3624 0160
Email
azamsongol@yahoo.com

5

Recruitment center
Name of recruitment center
Health Base No. 4
Full name of responsible person
Azam songol
Street address
Janbazan Square, Shushtarno
City
Shushtar
Province
Khouzestan
Postal code
8453464516

Phone
+98 61 3623 2106
Email
azamsongol@yahoo.com

6

Recruitment center
Name of recruitment center
Saheli Health Center
Full name of responsible person
Azam Songol
Street address
Najaf 16 Ave, Khane Sazi
City
Shushtar
Province
Khouzestan
Postal code
8453464516
Phone
+98 61 3623 2106
Email
azamsongol@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Abbas Motevalian
Street address
Shahid Hemat highway, Direction 2
City
tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 6650 9024
Fax
+98 21 8805 2248
Email
amotevalian@yahoo.com
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
Iran University of Medical Sciences
Full name of responsible person
Leila Amiri Farahani
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Health
Street address
Faculty of Nursing and Midwifery, Rashid Yasemi St., Vali-e-Asr Ave., Vanak Sq.
City
Tehran
Province
Tehran
Postal code
1996713883
Phone
+98 21 4365 1139
Fax
+98 21 4365 1138
Email
L.amirifarahani@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Leila Amiri Farahani
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Health
Street address
Faculty of Nursing and Midwifery, Rashid Yasemi St., Vali-e-Asr Ave., Vanak Sq.
City
Tehran
Province
Tehran
Postal code
1996713883
Phone
+98 21 4365 1139
Fax
+98 21 4365 1138
Email

L.amirifarahani@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Leila Amiri Farahani

Position
Associate prof.

Latest degree
Ph.D.

Other areas of specialty/work
Reproductive Health

Street address
Faculty of Nursing and Midwifery, Rashid Yasemi St., Vali-e-Asr Ave., Vanak Sq.

City
Tehran

Province
Tehran

Postal code
1996713883

Phone
+98 21 4365 1139

Fax
+98 21 4365 1138

Email
L.amirifarahani@gmail.com

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