

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2022

Determining the effect of a theory-based educational intervention on the prevention of brucellosis and livestock vaccination process

Protocol summary

Study aim

Determining the effect of educational intervention based on PRECEDE-PROCEED model in the prevention of brucellosis and livestock vaccination process in Lighvan village, East Azarbaijan province.

Design

Single blind clinical trial with control group

Settings and conduct

Training on brucellosis disease in the village of Lighvan, Tabriz

Participants/Inclusion and exclusion criteria

The criteria for the study include accommodation in the area and activity in livestock breeding; consenting to participate in the study and the absence of a history of brucellosis and receiving related training in this field in the past. Exit criteria include the inability to use the educational package intended for this study; including physical disabilities; including visual and auditory problems; limitation and absenteeism in more than 20% of the training sessions which can provide learners with the required level of learning; noticeable attention.

Intervention groups

Model-based intervention in ranchers

Main outcome variables

Reduction of brucellosis and increased brucellosis vaccination

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180304038945N1**

Registration date: **2018-12-24, 1397/10/03**

Registration timing: **registered_while_recruiting**

Last update: **2018-12-24, 1397/10/03**

Update count: **0**

Registration date

2018-12-24, 1397/10/03

Registrant information

Name

farhad bahadori

Name of organization / entity

Tarbeat modares

Country

Iran (Islamic Republic of)

Phone

+98 41 3331 9028

Email address

f.bahadori@modares.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-22, 1397/10/01

Expected recruitment end date

2019-06-22, 1398/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determining the effect of a theory-based educational intervention on the prevention of brucellosis and livestock vaccination process

Public title

Determining the effect of a theory-based educational intervention on the prevention of brucellosis and livestock vaccination process

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Livestock in Lighvan village Residence in the area and activities in the livestock sector Declaring consent to participate in the study Not having a history of brucellosis and receiving related training in this field in the past

Exclusion criteria:

The inability to use the educational package intended for this study, including physical inability, includes visual and auditory problems Limitation and absenteeism in more than 20% of the training sessions that can significantly affect learners' learning

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: 72

Randomization (investigator's opinion)

Randomized

Randomization description

Random software

Blinding (investigator's opinion)

Single blinded

Blinding description

The target group is the same stockbreeder

Placebo

Not used

Assignment

Other

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Tarbiat Modares University

Street address

Jalal Al-e Ahmad

City

tehran

Province

Tehran

Postal code

14115-111

Approval date

2018-05-16, 1397/02/26

Ethics committee reference number

IR.MODARES.REC.1397.001

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

Brucellosis

ICD-10 code

A23.0

ICD-10 code description

Brucellosis due to Brucella melitensis

Primary outcomes**1****Description**

Average scores of predisposing factors

Timepoint

Before the intervention, immediately after the intervention and 2 months after it

Method of measurement

Questionnaire

Secondary outcomes**1****Description**

Brucella antibody level in sheep

Timepoint

Before and after the vaccination season

Method of measurement

ELISA test or Rozbangal

Intervention groups**1****Description**

Intervention group: Farmers' behavior in vaccination against brucellosis and preventive behaviors. To do this, the intervention training is tailored to the target group for at least four sessions for an hour through the methods of the front line or using textual methods including brochures, etc.

Category

Behavior

2**Description**

Control group: The non-intervention control group and routine training will be given annually. Finally, after training, the effect of education was assessed in two intervention and control groups

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Lighvan village(individual livestock)
Full name of responsible person
Fazlollah Ghofranipour
Street address
lighvan village- Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
12345
Phone
+98 21 8288 0000
Email
ghoranipourf@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tarbiat modares
Full name of responsible person
Fazlollah Ghofranipour
Street address
jalale al ahmad
City
tehran
Province
Tehran
Postal code
14115-111
Phone
+98 21 8288 3869
Email
ghofranif@modares.ac.ir
Grant name
Research Deputy of Tarbiat Modares University
Grant code / Reference number
1410827
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tarbiat modares
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
Tarbiat modares
Full name of responsible person
Fazlollah Ghofranipour
Position
University professor
Latest degree
Ph.D.
Other areas of specialty/work
Health Promotion
Street address
jalale al ahmad
City
tehran
Province
Tehran
Postal code
14115-111
Phone
+98 21 8288 3869
Fax
+98 21 8288 3869
Email
ghofranf@modares.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tarbiat modares
Full name of responsible person
Fazlollah Ghofranipour
Position
University professor
Latest degree
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Jalal AleAhmad
City
tehran
Province
Tehran
Postal code
14115-111
Phone
+98 21 8288 3869
Email
ghofranf@modares.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Tarbiat modares
Full name of responsible person
Fazlollah Ghofranipour

Position

University professor

Latest degree

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Phone

+98 21 8288 3869

Email

ghofranf@modares.ac.ir

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

Yes - There is a plan to make this available

Title and more details about the data/document

Only part of the data, such as the original outcome information, will be available

When the data will become available and for how long

Two years after the start of the project and in 2019 onwards

To whom data/document is available

University researchers-veterinarians- and veterinarians related to the livestock industry

Under which criteria data/document could be used

Governmental centers with official permissions from relevant departments

From where data/document is obtainable

Contact by e-mail and phone number with Dr. Fazlollah Ghofranipour Ers-Tehran Jalal Al-Ahmad Tarbiat Modares University ghofranipourf@gmail.com 00982182880

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

Contact via emailCommunication via email and phone - if applicable, within a week to one month

Comments