

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 2026

### Comparison of the effect of two methods of distraction through inflating balloon and watching cartoons on DTP pain vaccine in school age children

#### Protocol summary

##### Summary

Immunization is a common painful event during childhood, which is typically performed without pain control. Regarding Importance of pain control in children, the purpose of this study was to investigate the effectiveness of the two methods of distraction (inflating a balloon and watch cartoons) on pain of Diphtheria -Tetanus- Pertussis (DTP) vaccine in school age children. In a clinical trial, 120 healthy at school age children who received DTP vaccine at Seyedoshohada health care center of Zahedan were randomly divided into three groups: In group1 one minute before and during the vaccination a distraction technique (blowing up balloons by children) was used. In group2 five minutes Cartoon Film was displayed on Lap tops (two minutes before and three minutes during and after vaccination) and in group 3 (control group), children were vaccinated according to routine instruction health centers. In all of groups, vaccine was injected in similar conditions and by a trained person. Primary outcomes included pain scores of children immediately after the DTP vaccine injection. The Pain score was assessed by the Behavioral Pain Scale (FLACC Scale).

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015080313889N2**

Registration date: **2016-01-02, 1394/10/12**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-01-02, 1394/10/12

##### Registrant information

##### Name

Hasan Robabi

##### Name of organization / entity

Zahedan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 54 1243 6643

##### Email address

robabi@zaums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor for research, Zahedan University of Medical Sciences

##### Expected recruitment start date

2015-06-22, 1394/04/01

##### Expected recruitment end date

2015-10-23, 1394/08/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the effect of two methods of distraction through inflating balloon and watching cartoons on DTP pain vaccine in school age children

##### Public title

Comparison of the effect of inflating balloon and watching cartoons on the pain of DTP vaccine in school age children

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion criteria: 1. having DTP vaccine qualification. 2. No history of surgery or hospitalization. 3. Not having

serious illness. 4. Eating breakfast before the injected vaccine. Exclusion criteria: Consuming sedative or hypnotic in last 24 hours.

#### Age

From **6 years** old to **6 years** old

#### Gender

Both

#### Phase

2

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **120**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Not blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

This is a clinical trial study. Randomized selecting sampling was performed through placing letters A, B and C in envelope which for each participant as follows: ask children select one of these letters, letters A ,B and C indicated of group injection1, 2, 3 respectively.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Zahedan University of Medical Sciences

##### Street address

Vice Chancellor for research, Zahedan University of Medical Sciences -Dr Hesabi Square- Zahedan

##### City

Zahedan

##### Postal code

98167-43463

#### Approval date

2015-06-20, 1394/03/30

#### Ethics committee reference number

IR.ZAUMS.REC.1394.62

## Health conditions studied

### 1

#### Description of health condition studied

Pain of injection vaccine

#### ICD-10 code

Z27.1

#### ICD-10 code description

Need for immunization against diphtheria-tetanus-pertussis, combined [DTP]

## Primary outcomes

### 1

#### Description

pain score of DTPvaccine injection

#### Timepoint

Immediately after DTPvaccine injection

#### Method of measurement

children Pain Scale(FLACC Scale)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

blowing up balloons by children one minute and during the vaccination

#### Category

Prevention

### 2

#### Description

Five minutes Cartoon Film displaying(two minutes before and three minutes during and after DTP vaccination)

#### Category

Prevention

### 3

#### Description

children were vaccinated according to routine health centers

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Syedoshohada Health Care Center

##### Full name of responsible person

Hasan Robabi

##### Street address

Syedoshohada Health Care Center - Shahid Rajaie str. Zahedan

##### City

Zahedan

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Vice chancellor for research,Zahedan University of Medical Sciences

**Full name of responsible person**

Dr M.Taheri

**Street address**

Vice chancellor for research, Zahedan University of Medical Sciences -Dr Hesabi Square- Zahedan

**City**

Zahedan

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice chancellor for research,Zahedan University of Medical Sciences

**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**

Zahedan University of Medical Sciences

**Full name of responsible person**

Fatihe Kerman Saravi

**Position**

MSc/ Instructor of Nursing, Zahedan Nursing and Midwifery School

**Other areas of specialty/work****Street address**

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## Person responsible for scientific inquiries

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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*