Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Study of effectiveness of evaporative spray on intravenous catheterization pain in Imam Reza Hospital in Sirjan 2014

Protocol summary

Summary

Objectives: This study aims to determine the effectiveness of evaporative spray on intravenous catheterization pain in Imam Reza Hospital in Sirjan 2014. Design: A random designs Setting and conduct: The sample were randomized to either an intervention group that received the evaporative spray and control group It does not do anything about them. This is randomly that Patients Referred in couple days a week the experimental group and days of the week Assigned to the control group. Tools used include: behavioral scale and a numerical scale to measure pain. Participants including major: The sample have been selected of children hospitalized in Imam Reza Hospital in Sirjan that 60 pediatric Hospitalization in aged 6-12 years. Exclusion criteria: Venipuncture to diagnosis doctor; Ability to respond to visual analog scale; Parental consent to participate in research; Children's oral consent to participate in research; Accompanied by a parent in the study and first venipuncture experience when admitted. Inclusion criteria: use of drugs that alter children's consciousness; Sensitivity to anesthetic spray and cold; Specific diseases (thyroid disorders, epilepsy, peripheral vascular disease or disease that causes loss of consciousness in children); Reject to participate; Severe pain; Urgent need for venipuncture; Get another non-pharmacological methods of pain control during the procedure and deficiency of physical and mental health to the extent that it is prevented from doing research (word - mentally - visual – physica). Main outcome measures: Pain

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201406057844N4**
Registration date: **2014-11-19, 1393/08/28**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2014-11-19, 1393/08/28

Registrant information

Name
Mansour Arab
Name of organization / entity
Kerman University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 34 1320 5179
Email address
marab@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research (Research & Technology), Kerman University of Medical Sciences

Expected recruitment start date

2014-01-20, 1392/10/30

Expected recruitment end date

2014-06-20, 1393/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of effectiveness of evaporative spray on intravenous catheterization pain in Imam Reza Hospital in Sirjan 2014

Public title

Evaporative spray effect on reducing injection pain in children

Purpose
Health service research
Inclusion/Exclusion criteria
Exclusion criteria: Venipuncture to diagnosis doctor; Ability to respond to visual analog scale; Parental consent to participate in research; Children's oral consent to participate in research; Accompanied by a parent in the study and first venipuncture experience when admitted. Inclusion criteria: use of drugs that alter children's consciousness; Sensitivity to anesthetic spray and cold; Specific diseases (thyroid disorders, epilepsy, peripheral vascular disease or disease that causes loss of consciousness in children); Reject to participate; Severe pain; Urgent need for venipuncture; Get another non-pharmacological methods of pain control during the procedure and deficiency of physical and mental health to the extent that it is prevented from doing research (word - mentally - visual – physica).
Age
From **6 years** old to **12 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

1

Registry name
Not in place
Secondary trial Id
Not in place
Registration date
empty

2

Registry name
در جایی ثبت نشده است
Secondary trial Id
در جایی ثبت نشده است
Registration date
empty

Ethics committees

1

Ethics committee
Name of ethics committee
The ethics committee of Kerman university of medical sciences
Street address
The ethics committee, second floor, Kerman university of medical sciences,Republic Blvd
City
Kerman
Postal code
۷۶۱۸۷۴۷۶۵۳
Approval date
2010-09-23, 1389/07/01
Ethics committee reference number
k/92/491

Health conditions studied

1

Description of health condition studied
Children hospitalized in Imam Reza Hospital in Sirjan
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
pain
Timepoint
During and immediately after the intervention.
Method of measurement
\ numeric scale & behavioral scale to measure pain

Secondary outcomes

1

Description
Skin effects
Timepoint
During and after the intervention
Method of measurement
Observation

Intervention groups

1

Description
Intervention group: Researcher prior to venipuncture to children and their parents participated in intervention group, branoll and supplies for venipuncture showed and describeto the about how to open up and fix IV. In addition to this equipment, evaporative spray in test

group was added, and the children and their families was explained that the purpose of using the spray is only to reduce pain. Evaporative spray used in this study is freeze spray product in Italy, the exclusive representative of the company of modern medicine is expensive equipment. Vapocoolant sprays are rapid-acting alternatives to topical anesthetics. The material used in spray is isopropyl alcohol. They provide transient anesthesia via evaporation-induced skin cooling, which reduces pain. Evaporative spray after being sprayed, destroys the skin hot and with disabling pain receptors can cause temporary numbness. The vapocoolant spray that we studied is a nonflammable, nontoxic and ozone-friendly spray. It is easy to apply, is less expensive than alternatives, works instantaneously, does not require a needle or needle-like device and is relatively innocuous. Side effects include rare allergic reactions and minor temporary skin changes. Unfortunately, skin changes may become permanent if the topical spray exceeds 10 seconds because severe local hypothermia may cause the death of local cells Area of the venipuncture was bent elbow. In the test group before venipuncture, evaporative spray was used,It was to be sprayed at room temperature by the researcher from a distance of25-30 cm for 5-10 seconds until the white and pale skin would have and Because of the short-acting, 40-30 seconds after the vessel began taking by special nurse.In addition, the intervention group before venipuncture first spray was and after the area was Sterilization. To reduce the effect of confounding factors, the sterilization procedures and venipuncture was performed completely identical in intervention group. Practice of opening a vein in all of the sample, in intervention group were performed by nurses with pediatric experience. Behavioral pain scale in children during procedures in intervention group were observed and recorded by the nurse researcher. After injection pain in children by means of numerical pain was assessed by the children themselves..

Category

Treatment - Drugs

2

Description

Control group: In the control group used of placebo spray that Similar to the form used in the intervention group but with normal Saylyn . How to use a placebo spray Practice of opening vein and the instruments and area of the venipuncture in Control group were similar to intervention group. In the Control group before venipuncture, placebo spray was used,It was to be sprayed at room temperature by the researcher from a distance of25-30 cm for 5-10 seconds, 40-30 seconds after the vessel began taking by special nurse.In addition, the Control group before venipuncture first spray was and after the area was Sterilization. Practice of opening a vein in all of the sample, in Control group were performed by nurses with pediatric experience. Behavioral pain scale in children during procedures in Control group were observed and recorded by the nurse researcher. After injection pain in children by means of numerical pain was assessed by the children themselves

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza (AS) Sirjan

Full name of responsible person

Dr kazoos rayani

Street address

Chamber of Presiden, second floor,School of Nursing and Midwifer, Haftbagh, Kerman

City

Sirjan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Kerman University of Medical Sciences

Full name of responsible person

Abbas Pardakhti

Street address

Medical Science Vice chancellor for research, Medical Science University of kerman, Of the university, Islamic Republic of Iran , Kerman

City

Kerman

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, Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Masood Rayani

Position

PhD in Nursing، Nursing Midwifery Directorate

Other areas of specialty/work

Street address

Chamber of Presiden, second floor,School of Nursing and Midwifery, Haftbagh, Kerman

City

Kerman

Postal code

۷۶۱۸۷۴۷۶۵۳

Phone

+98 34 1322 5077

Fax

Email

mryani@kmu.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Mansor Arab

Position

Faculty

Other areas of specialty/work

Street address

The second room on the right, second floor, Nursing and Midwifery, Haftbagh, Kerman

City

Kerman

Postal code

۷۶۱۸۷۴۷۶۵۳

Phone

+98 34 1226 0588

Fax

Email

marab112004@yahoo.com

Web page address

Person responsible for updating data

Contact

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