Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparing the analgesic effects of oral Glucose, sterile water, Acetaminophen and Breastfeeding mothers in reducing neonatal pain.

Protocol summary

Summary

The purpose of this study is to select the best method to reduce pain in neonatal during painful procedures. Inclusion criteria of this study consists of the term and healthy newborns that admitted to hospital and placed under the blood sampling .The blood-sampling of the neonates will be done from the radial artery. Neonates will be divided into 4 groups. The exclusion criteria of the study are anomalies, asphyxia, previous painful intervention such as circumcision . In the first group 1ml of oral glucose50% as analgesic substance will be used two minutes before the procedure and up to 45 seconds , the neonate will be examined. In the second group , breastfeeding of mothers will be used two minutes before the start of the procedure. In the third group oral acetaminophen 15mg/kg/dose will be used two hours before the procedure and the neonates up to 45 seconds later will be evaluated. In the fourth group ,1ml of sterile water will be used two minutes before the procedure and up to 45 seconds later, the neonate will be evaluated. The tool of measuring pain in neonates is the COVERS SCALE, This tool is based on 6 different physiologic and behavioral standards that each of these factors has a rating of 2-1-1.The scale of the physiologic include heart rate, blood pressure, oxygen needs ,how to breathe (increase and reduction of the number of breathing or apnea), and behavioral changes, including a demonstration figures, State of rest, the movements of the body. minimum and maximum rates 0-12 is obtained

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201205319916N1**
Registration date: **2012-09-16, 1391/06/26**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2012-09-16, 1391/06/26

Registrant information

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Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Hamedan University of Medical Sciences

Expected recruitment start date

2012-04-20, 1391/02/01

Expected recruitment end date

2013-02-19, 1391/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the analgesic effects of oral Glucose, sterile water, Acetaminophen and Breastfeeding mothers in reducing neonatal pain.

Public title

Comparing the analgesic effects of oral Glucose, sterile water, Acetaminophen and Breastfeeding mothers in reducing neonatal pain.

Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: all the term neonates and healthy with a weight of 2500 to 4000 grams admitted just because icter in hamedan hospitals and under the blood sampling. Exclusion criteria: anomalies at birth; asphyxia; prior painful intervention; circumcision, injection and admission for any cause other than jaundice.
Age
From **1 year** old to **28 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **128**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Hamedan Univercity of Medical Sciences Ethics Committee
Street address
Fahmideh aveniue
City
Hamedan
Postal code
Approval date
2012-04-16, 1391/01/28
Ethics committee reference number
16/70/7/85/پ

Health conditions studied

1

Description of health condition studied
rediuce pain
ICD-10 code
y84-7
ICD-10 code description
Other medical procedures as the cause of abnormal reaction of the patient, or of later complication, without mention of misadventure at the time of the procedure

Primary outcomes

1

Description
pain
Timepoint
untle 45 second after intrvention
Method of measurement
covers scale

Secondary outcomes

1

Description
reduce of pain
Timepoint
45 second
Method of measurement
covers scale

Intervention groups

1

Description
Of 128 newborn in this study are examined, in the first group the .32 neonate from 1ml of oral glucose 50% of as analgesic substance will be used two minutes before the process and up to 45 seconds later the neonate assesmented
Category
Treatment - Drugs

2

Description
Of 128 neonate in this study. 32 the neonates in the Group II will be examined. the breast milk of two minutes before the start of the process will be used and the neonate up to 45 seconds later followed
Category
Treatment - Drugs

3

Description
Of the 128neonate in this study. 32 the neonates in the third group, from oral acetaminophen 15 mg/kg/dose will be used two hours before the procedure and the noenates up to 45 seconds later will be evaluated.
Category
Treatment - Drugs

4

Description
Of the 128 neonate in this study. 32 the neonates in Group IV, from 1ml sterile water two minutes, before the procedure will be used and to 45 seconds later, the neonate will be evaluated.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Besat hospital
Full name of responsible person
Zohreh shalchi
Street address
Resalat squar
City
Hamedan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences Hamedan univercity of medical
Full name of responsible person
Dr Fateme Eghbalian
Street address
Besat hospital
City
Hamedan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Hamedan University of Medical Sciences Hamedan univercity of medical
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
Hamedan University of Medical Sciences
Full name of responsible person
Zohreh Shalchi
Position
MD, Pediatric assistant
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Person responsible for scientific inquiries

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Person responsible for updating data

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Web page address

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