

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

Name

Zohreh Shalchi

Name of organization / entity

Hamedan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0818

Email address

z.shalchi@umsha.ac.ir

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 University of Medical Sciences Ethics Committee

Street address

Fahmideh avenue

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

reduce 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
university 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
university 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

Other areas of specialty/work

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Web page address	<i>empty</i>
Sharing plan	Informed Consent Form
	<i>empty</i>
Deidentified Individual Participant Data Set (IPD)	Clinical Study Report
<i>empty</i>	<i>empty</i>
Study Protocol	Analytic Code
<i>empty</i>	<i>empty</i>
Statistical Analysis Plan	Data Dictionary
	<i>empty</i>