Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of Au-Da-libur water and placebo on infections and falling time of umbilical cord

Protocol summary

Study aim
Comparison of the effect of Au-Da-libur water and placebo on infections and falling time of umbilical cord
Design
A clinical trial has been conducted with randomized control and intervention groups. The sample size consists of 80 neonates. Individuals will be randomly assigned to one of the two groups by using the table of random numbers.
Settings and conduct
The present study will be conducted at Kosar Hospital of Qazvin. In the intervention group, Au-Da-libur water will be used (3 times/day). Distilled water was used in the placebo group. The length time of the umbilical cord falls and the infection rate will be recorded. Finally, the data will be entered into SPSS software and statistical tests will be done.
Participants/Inclusion and exclusion criteria
Healthy newborns Gestational age ≥35 weeks Birth weight ≥ 2.5 kg
Intervention groups
Treatment group: treatment with Au-Da-libur water
Placebo group: treatment with distilled water
Main outcome variables
Time of umbilical cord falling down (days) Infection rate

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20190122042456N1**
Registration date: **2019-05-06, 1398/02/16**
Registration timing: **prospective**

Last update: **2019-05-06, 1398/02/16**
Update count: **0**
Registration date
2019-05-06, 1398/02/16

Registrant information
Name
Samane Lashgari
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 28 3332 8708
Email address
s.lashgari@qums.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-05-22, 1398/03/01
Expected recruitment end date
2019-12-22, 1398/10/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of Au-Da-libur water and placebo on infections and falling time of umbilical cord

Public title
The effect of Au-Da-libur water on falling time of umbilical cord
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Healthy newborns Gestational age ≥35 weeks Birth weight ≥ 2.5 kg
Exclusion criteria:

The presence of underlying or acquired illness Medical interventions on the newborn

Age
From **1 day** old to **1 day** old

Gender
Both

Phase
1

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
In the present study, individuals will be randomly assigned to one of the two intervention and control groups by using the table of random numbers. There is no precondition for assigning individuals to groups. The randomization unit is Individual. Every participant will have an equal chance of being in each of the groups. Allocation concealment samples are done by the people of the center that they do not have any information about the researcher's aim.

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
Ethics Committee of Qazvin University of Medical Sciences

Street address
Dadgostari crossroad, Shahid Bahonar Blvd. Qazvin, Iran

City
Qazvin

Province
Qazvin

Postal code
4595134159

Approval date
2019-01-12, 1397/10/22

Ethics committee reference number
IR.QUMS.REC.1397.292

Health conditions studied

1

Description of health condition studied
Umbilical cord infection

ICD-10 code
P02.6

ICD-10 code description
Fetus and newborn affected by other and unspecified conditions of umbilical cord

Primary outcomes

1

Description
Time of umbilical cord falling down

Timepoint
Daily visits until umbilical cord falls

Method of measurement
Observational

2

Description
Infection rate

Timepoint
Daily visits until umbilical cord falls

Method of measurement
Observational

Secondary outcomes

1

Description
Au-Da-libur water side effects

Timepoint
Daily visits until umbilical cord falls

Method of measurement
Observational

Intervention groups

1

Description
Intervention group: treatment with Au-Da-libur water

Category
Treatment - Drugs

2

Description
Control group: Treatment with distilled water (placebo)

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Kosar Hospital
Full name of responsible person
Samaneh Lashgari
Street address
Kosar Alley, Shahid Talaghani St. Qazvin
City
Qazvin
Province
Qazvin
Postal code
1317634156
Phone
+98 28 3323 6374
Fax
+98 28 3323 6378
Email
itkosar@qums.ac.ir
Web page address
http://hoskosar.qums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Amir Peymani
Street address
Dadgostari crossroad, Shahid Bahonar Blvd. Qazvin, Iran
City
Qazvin
Province
Qazvin
Postal code
5981134197
Phone
+98 28 7006 3333
Email
apeymani@qums.ac.ir
Web page address
http://vcr.qums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Qazvin University of Medical Sciences
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
Qazvin University of Medical Sciences
Full name of responsible person
Murtaza Habibi
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
Street address
Qods Sq., Shahid beheshti Blvd., Qazvin, Iran
City
Qazvin
Province
Qazvin
Postal code
3415945951
Phone
+98 28 3333 4807
Email
mhabibi@qums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Samaneh Lashgari
Position
M.D. student
Latest degree
Medical doctor
Other areas of specialty/work
Pediatrics
Street address
Qods Sq., Shahid Bahonar Blvd., Qazvin, Iran
City
Qazvin
Province
Qazvin
Postal code
3419759811
Phone
+98 28 3333 7006
Email
s.lashgari@gums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Samaneh Lashgari

Position
M.D. student
Latest degree
Medical doctor
Other areas of specialty/work
Pediatrics
Street address
Qods Sq., Shahid Bahonar Blvd., Qazvin, Iran
City
Qazvin
Province
Qazvin
Postal code
3419759811
Phone
+98 28 3333 7006
Email
s.lashgari@qums.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
Yes - There is a plan to make this available
Data Dictionary
Not applicable
Title and more details about the data/document
All data is published in Excel format without mentioning patient names.
When the data will become available and for how long
The data will be released from July 2022 for one month.
To whom data/document is available
Medical students, researchers at medical research centers and professors of medical sciences universities
Under which criteria data/document could be used
Comparison of data with other experimental data is allowed. If the article is published, mention should be made of the names of the persons who own the data.
From where data/document is obtainable
The main executor of clinical trial
What processes are involved for a request to access data/document
Submitting a request by the applicant and submitting a letter from the authorized centers.
Comments