

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Comparing the success rate of the three urine sampling methods with Catheterization, Suprapubic Aspiration with and without Guidance in Neonates and Infants younger than three month suspicious to Urinary Tract Infection

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

To determine and compare the success rate of three urine sampling methods with catheterization, suprapubic aspiration with and without guidance in infants suspicious to urinary tract infection

Last update: **2018-04-09, 1397/01/20**

Update count: **0**

Registration date

2018-04-09, 1397/01/20

Design

clinical trial with control group

Registrant information

Name

Hamidreza Badeli

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Settings and conduct

Neonates and infants hospitalized in 17 Shahrivar Hospital suspicious to Urinary Tract Infection are divided into 3 therapeutic groups: A, B, and C according to block randomization. Group A: Sampling with Catheterization Group B: Sampling with Suprapubic Aspiration Group C: Sampling with Ultrasonography-guided Suprapubic Aspiration There is a maximum limit of three-time efforts for sampling

Recruitment status

Recruitment complete

Funding source

Participants/Inclusion and exclusion criteria

Entry condition: All the Neonates and Infants younger than 3 month suspicious to Urinary Tract Infection No-entry conditions: Infection of the examined -skin site Anatomical disorders of Urinary Tract Bleeding Disorders and Uncorrected Thrombocytopenia Enlarged abdomen and Intra-abdominal Viscera

Expected recruitment start date

2017-12-22, 1396/10/01

Expected recruitment end date

2018-12-22, 1397/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Intervention groups

Group A: Catheterization Group B: Suprapubic Aspiration Group C: Ultrasonography-guided Suprapubic Aspiration

Main outcome variables

Overall success rate of each sampling method

Scientific title

Comparing the success rate of the three urine sampling methods with Catheterization, Suprapubic Aspiration with and without Guidance in Neonates and Infants younger

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090111001545N3**

Registration date: **2018-04-09, 1397/01/20**

than three month suspicious to Urinary Tract Infection

Public title
Comparing the success rate of the three urine sampling methods with Catheterization, Suprapubic Aspiration with and without Guidance in neonates and infants younger than three month with Urinary Tract Infection

Purpose
Diagnostic

Inclusion/Exclusion criteria
Inclusion criteria:
All the Neonates and Infants younger than 3 month suspicious to Urinary Tract Infection
Exclusion criteria:
Infection of the examined -skin site Anatomical disorders of Urinary Tract Bleeding Disorders and Uncorrected Thrombocytopenia Enlarged abdomen and Intra-abdominal Viscera

Age
From **1 day** old to **3 months** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **114**

Randomization (investigator's opinion)
Randomized

Randomization description
Sampling will be performed by randomization method. Neonates and infants will be classified into 3 therapeutic groups by block randomization.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Guilan University of Medical Sciences

Street address

Namjou Ave,Shadid Siadati St,Rasht

City

Rasht

Province

Guilan

Postal code

4144654839

Approval date

2016-12-15, 1395/09/25

Ethics committee reference number

IR.GUMS.REC.1395.365

Health conditions studied

1

Description of health condition studied

Success rate of urine sampling methods

ICD-10 code

P39.3

ICD-10 code description

Neonatal urinary tract infection

Primary outcomes

1

Description

Overall success rate of each sampling method

Timepoint

Three times

Method of measurement

Catheterization,Suprapubic aspiration without guidance,Suprapubic aspiration with guidance

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: The group in which urine sample is collected by Catheterization

Category

Diagnosis

2

Description

Intervention group 2: The group in which urine sample is collected by Suprapubic Aspiration

Category

Diagnosis

3

Description

Intervention group 3: The group in which urine sample is collected by Ultrasonography-guided suprapubic Aspiration

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center
17-Shahrivar Children Hospital
Full name of responsible person
Hamidreza Badeli
Street address
Namjou Ave, Shadid Siadati St, Rasht
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17shahrivar@gums.ac.ir
Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Shadman Nemati
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Rasht 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
Rasht University of Medical Sciences
Full name of responsible person
Hamidreza Badeli
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
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Person responsible for scientific inquiries

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Person responsible for updating data

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

regarding the ethical issues and confidentiality

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available