

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Dec 2020

### 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)

##### Phone

+98 13 1322 9523

##### Email address

badeli@gums.ac.ir

#### 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

#### 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

#### 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 examed -skin site Anatomical disorders of Urinary Tract Bleeding Disorders and Uncorrected Thrombocytopenia Enlarged abdomen and Inrta-abdominal Viscera

#### 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

#### 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

#### 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  
**Street address**  
Namjou Ave, Shadid Siadati St, Rasht  
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research@gums.ac.ir  
**Web page address**  
**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

### Contact

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Assistant Professor  
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## Person responsible for updating data

### Contact

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**Full name of responsible person**

Hamidreza Badeli

**Position**

Associate Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Pediatrics

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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