

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

Evaluation of the effect of time and temperature on urine culture results in children using urine bag or midstream sample.

Protocol summary

Summary

The aim of this study is to evaluate the effect of time and temperature on children's urine culture (U/C) results using bag or midstream sampling. This is a randomized not blinded clinical trial on 60 patients. We will assign 60 patients into 2 groups. Urine sampling will be done using bag and midstream methods for groups 1 and 2, respectively. U/C results of samples obtained within 1 hour from sampling (as true results) would be compared with the results of 2 and 4 hours after sampling (as results containing false positives) for each patient. 2 and 4 hour samples would be randomly kept in refrigerator or out of refrigerator to see if keeping in cold place can decrease the rate of false positive.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201110287892N3**

Registration date: **2011-11-15, 1390/08/24**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2011-11-15, 1390/08/24

Registrant information

Name

Anoosh Azarfar

Name of organization / entity

Mashhad University of Medical Sciences, Faculty of Nursing and Midwifery

Country

Iran (Islamic Republic of)

Phone

+98 51 1606 1227

Email address

azarfara@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Research center for children's health of Tabriz Medical University

Expected recruitment start date

2011-11-22, 1390/09/01

Expected recruitment end date

2012-02-20, 1390/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of time and temperature on urine culture results in children using urine bag or midstream sample.

Public title

Influence of time and temperature on children's urine culture result

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria: All patients under 12 years of age who refer to the hospital for U/A and U/C and their urine samples have brought to the lab within 1 hour Exclusion criteria: inpatient cases; patients older than 12; patients with insufficient urine samples to perform urine culture for latter hours; urine samples brought to the lab after 1 hour from sampling

Age

To **12 years** old

Gender

Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **240**

Randomization (investigator's opinion)
N/A

Randomization description

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 Tabriz University of Medical Sciences

Street address
Vice-Chancellor for Research, Tabriz University of Medical Sciences, Daneshgah square

City
Tabriz

Postal code
51665118

Approval date
2010-03-06, 1388/12/15

Ethics committee reference number
2735/4/5

Health conditions studied

1

Description of health condition studied
Urinary tract infection

ICD-10 code
N39.0

ICD-10 code description
Urinary tract infection, site not specified

Primary outcomes

1

Description
Urine Culture (U/C)

Timepoint
2 and 4 hours

Method of measurement

Microscope

Secondary outcomes

1

Description
Urine culture positive

Timepoint
2 and 4 hours

Method of measurement
Microscope

Intervention groups

1

Description
Urine sampling using urine bag

Category
Diagnosis

2

Description
Urine sampling using midstream sampling

Category
Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center
Tabriz Children's hospital

Full name of responsible person
Anoosh azarfar

Street address
Children's hospital-sheshgelan st.

City
Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Research center for children's health

Full name of responsible person
mohammad barzegar, center's chief

Street address
Children's hospital-sheshgelan st.

City
Tabriz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source

Research center for children's health

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**

Tabriz Medical University

Full name of responsible person

Anoosh azarfar

PositionAssistant professor, Subspecialist in pediatrics
nephrology**Other areas of specialty/work****Street address**

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Tabriz Medical University

Full name of responsible person

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PositionAssistant professor, Subspecialist in pediatrics
nephrology**Other areas of specialty/work****Street address**

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Postal code**Phone****Fax****Email****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