

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 2026

### Efficacy of procalcitonin level measurement in diagnosis of early antimicrobial resistance in patient with sepsis in emergency department

#### Protocol summary

##### Summary

**Introduction:** Early detection of sepsis is one of the important aspects of today's emergency care. The availability of antibiotics has improved the patient care, but early diagnosis and correct antibiotic selection is still a challenge. Procalcitonin is one of the latest sepsis biomarkers, which have shown to be useful in tracking the course of sepsis and antibiotic response. The aim of this study is to determine the feasibility of using procalcitonin readings in early prediction, before the antibiogram results are available (first 48 hours), in patients with sepsis coming to emergency department. Patients and Methods: The study is a prospective randomized clinical trial conducted in Imam Hossein Medical Center emergency department, Tehran, Iran. All patients with clinical findings suggesting sepsis or systemic inflammatory response syndrome who give consent will enter the study. Patients with systemic inflammation of non bacterial origin, viral or parasitic infections, patients who receive corticosteroids on immunosuppressive drugs will be excluded. Also all patients with a history of immunodeficiency or central venous catheter will be excluded. The sampling continues until 150 patients are entered into the study. A predesigned questionnaire will be used to document the patients' clinical findings. Peripheral blood sample for culturing and antibiogram and procalcitonin measurement, as well as other routine laboratory tests will be taken. The procalcitonin levels will be checked before, six, and twenty four hours after the initiation of antibiotic therapy. The procalcitonin measurement will be done using immunoluminometric measuring (Brahms PCT, Diasorin, USA). We will not interfere with any aspects of treatment and antibiotic therapy. Antibiotic change, if necessary, will be carried on based on patients' clinical findings and ultimately based on antibiogram. The results of procalcitonin readings will be compared to blood culture, urine culture, CSF cultures and antibiogram results, clinical findings and patients' outcome. We will calculate the sensitivity

and specificity of procalcitonin in predicting the antibiotic response compared to antibiogram as the gold standard.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201102065774N1**

Registration date: **2011-07-24, 1390/05/02**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2011-07-24, 1390/05/02

##### Registrant information

##### Name

Ali Arhami Dolatabadi

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8825 1234

##### Email address

ali\_arhami@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

vice-chancellor for research, Shahid Beheshti University of Medical Sciences

##### Expected recruitment start date

2011-07-23, 1390/05/01

##### Expected recruitment end date

2012-07-22, 1391/05/01

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Efficacy of procalcitonin level measurement in diagnosis of early antimicrobial resistance in patient with sepsis in emergency department

**Public title**

The role of procalcitonin in sepsis

**Purpose**

Diagnostic

**Inclusion/Exclusion criteria**

Inclusion criteria: All patients with clinical findings suggesting sepsis, All patients with clinical findings of systemic inflammatory response syndrome Exclusion criteria: All patients with clinical findings of systemic inflammatory response syndrome from non bacterial origin, viral or parasitic infections, patients who receive corticosteroids on immunosuppressive drugs, history of immunodeficiency, patient with central venous catheter and premature infant

**Age**

No age limit

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **150**

**Randomization (investigator's opinion)**

N/A

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Single

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Shahid Beheshti University of Medical Scinces

**Street address**

Tabnank St, Yaman St, Shahid Chamran highway

**City**

Tehran

**Postal code**

1985717443

**Approval date**

2011-02-27, 1389/12/08

**Ethics committee reference number**

96

**Health conditions studied****1****Description of health condition studied**

Sepsis

**ICD-10 code**

B90-B94

**ICD-10 code description**

Sequelae of infectious and parasitic diseases

**2****Description of health condition studied**

procalcitonin

**ICD-10 code**

R70-R79

**ICD-10 code description**

Abnormal findings on examination of blood, without diagnosis

**Primary outcomes****1****Description**

procalcitonin

**Timepoint**

before and 6 hr and 24 hr after empiric antibiotic administration

**Method of measurement**

Immunoluminoassay ng/mL

**Secondary outcomes****1****Description**

Antibiogram

**Timepoint**

One time

**Method of measurement**

Resistantant, sensitive

**2****Description**

Empiric antibiotic

**Timepoint**

one time, after blood sampling withdrawn

**Method of measurement**

based on united state infectious disease guideline

### 3

**Description**

Time of clinical sign improved

**Timepoint**

Daily

**Method of measurement**

Clinical sign( fever)

### 4

**Description**

Prognosis(death)

**Timepoint**

Death

**Method of measurement**

Clinically

### 5

**Description**

Prognosis(life)

**Timepoint**

Life

**Method of measurement**

Clinically

### 6

**Description**

Thyroid tumor

**Timepoint**

One time

**Method of measurement**

Clinical and laboratory investigation

### 7

**Description**

Immunosuppression

**Timepoint**

One time

**Method of measurement**

Clinical and laboratory investigation

## Intervention groups

### 1

**Description**

Immunoluminoassy of serum procalcitonin in patient with sepsis, Blood sampling, Lumbar puncture

**Category**

Diagnosis

## Recruitment centers

### 1

**Recruitment center****Name of recruitment center**

Immam Hosein hospital

**Full name of responsible person**

Ali Arhami Dolatabadi

**Street address**

Shahid Madani St, Immam Hosein hospital,

**City**

Tehran

## Sponsors / Funding sources

### 1

**Sponsor****Name of organization / entity**

vice-chancellor for research of Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Mohammad Rahmati Roodsari

**Street address**

Tabnak St, Yaman St, Shahid Chamran highway

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Tehran

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

vice-chancellor for research of Shahid Beheshti University of Medical Sciences

**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**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Ali Arhami Dolatabadi

**Position**

Emergency medicin, Assistant professor

**Other areas of specialty/work****Street address**

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## Person responsible for scientific inquiries

### Contact

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## 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*

## Person responsible for updating data

### Contact

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**