

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 Sciences

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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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