

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Examination of proinflammatory and inflammatory cytokines in full-term neonates suspected of sepsis prior to and 12 hours after antibiotic therapy (pilot study)

Protocol summary

Summary

The purpose of this study is to understand whether antibiotics can cause changes in blood cytokine levels or not. Inclusion criteria: All healthy full-term babies, having healthy mothers and normal Apgar scores, suspected of sepsis and candidates for antibiotic treatment in the NICU of Vali-e Asr Hospital. Exclusion criteria: Infants with positive blood cultures, infants with positive cerebrospinal fluid culture, infants being treated with corticosteroids, infants whose mothers were treated with corticosteroids or magnesium sulphate at least one week prior to delivery, infants whose mothers received antibiotics prior to delivery, cord acidosis and birth asphyxia, infants that are intravenously fed, and infants of ill mothers. This is an observational before and after pilot study that examines forty healthy full-term babies suspected of sepsis and candidates for antibiotic treatment in the NICU of Vali-e Asr Hospital. This examination involves taking 1 cc of blood from the infants prior to administration of antibiotics and 1 cc twelve hours after administration of the antibiotics. Using the ELISA test, IL-8, IL-6, IL-1, and TNF- α serum levels will be examined.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201504289568N13**
Registration date: **2015-06-02, 1394/03/12**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-06-02, 1394/03/12

Registrant information

Name

Golnaz Rezaeizadeh

Name of organization / entity

Maternal Fetal Neonatal Research Center, Tehran
University of Medical Sciences, Tehran, Iran

Country

Iran (Islamic Republic of)

Phone

+98 21 6119 2357

Email address

mfnhrc@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran university of medical sciences and Shahed university

Expected recruitment start date

2015-05-22, 1394/03/01

Expected recruitment end date

2016-05-21, 1395/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Examination of proinflammatory and inflammatory cytokines in full-term neonates suspected of sepsis prior to and 12 hours after antibiotic therapy (pilot study)

Public title

Examination of the Effect of Antibiotics on Inflammatory Factors in Neonates

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: All healthy full-term babies, having healthy mothers and normal Apgar scores, suspected of sepsis and candidates for antibiotic treatment in the NICU of Vali-e Asr Hospital. Exclusion criteria: Infants with positive blood cultures, infants with positive cerebrospinal fluid culture, infants being treated with corticosteroids, infants whose mothers were treated with corticosteroids or magnesium sulphate at least one week prior to delivery, infants whose mothers received antibiotics prior to delivery, cord acidosis and birth asphyxia, infants that are intravenously fed, and infants of ill mothers.

Age

To 28 days old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 40

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

Tehran University of Medical Sciences

Street address

Ethics committee of Tehran University of Medical Sciences, 6 th floor of Tehran University of Medical

City

Tehran

Postal code

Approval date

2015-04-28, 1394/02/08

Ethics committee reference number

93-03-91-26214-145324

Health conditions studied

1

Description of health condition studied

Bacterial sepsis of newborn

ICD-10 code

P36

ICD-10 code description

Bacterial sepsis of newborn

Primary outcomes

1

Description

IL-1 β

Timepoint

just before and 12 hrs after intervention

Method of measurement

ELISA, pg/ml

2

Description

IL-6

Timepoint

just before and 12 hrs after intervention

Method of measurement

ELISA, pg/ml

3

Description

IL-8

Timepoint

just before and 12 hrs after intervention

Method of measurement

ELISA, pg/ml

4

Description

TNF- α

Timepoint

just before and 12 hrs after intervention

Method of measurement

ELISA, pg/ml

Secondary outcomes

empty

Intervention groups

1

Description

Antibiotic therapy with ampicillin+amikacin or rarely vancomycin+meropenem

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Maternal Fetal Neonatal Research Center

Full name of responsible person

Golnaz Rezaeizadeh

Street address

Vaiasr hospital, Imam Khomeini Hospital complex,
Keshavarz blv, Tehran, Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahed university

Full name of responsible person

Tooba Ghazanfari

Street address

Medical faculty of Shahed university- Abdollahzadeh
St., Keshavarz blv, Tehran, Iran

City

Tehran

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

Yes

Title of funding source

Shahed university

Proportion provided by this source**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

2

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mojgan Karbakhsh

Street address

Ghods St., Keshavarz blv, Tehran, Iran

City

Tehran

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

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source**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

Maternal Fetal Neonatal Research Center, Tehran
University of Medical Sciences

Full name of responsible person

Golnaz Rezaeizadeh

Position

researcher/MD

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

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Person responsible for scientific inquiries

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Name of organization / entity

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University of Medical Sciences

Full name of responsible person

golnaz rezaeizadeh

Position

researcher/MD

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

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Person responsible for updating data

Contact

Name of organization / entity

Maternal Fetal Neonatal Research Center,Tehran
University of Medical Sciences

Full name of responsible person

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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