Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The study of efficacy of Pentoxifylline in late Sepsis in preterm neonate(Trial clinical randomized)

Protocol summary

Study aim

The study of efficacy of Pentoxifylline in late sepsis in preterm neonate

Design

Randomized,paralled group,single blind clinical trial design include 40 patients,phase 3.

Settings and conduct

This study will be conducted on preterm neonate with diagnosis of late onset sepsis who hospitalized in NICU of Alzahra hospital.A randomized, clincal trial as a pilot study, will be done on 40 preterm with known sepsis.these neonates are randomly divided into two groups.one group will be receive Pentoxyfilin orally at a dose of 10 mg/kg every 8 hours for 6 day with routin antibiotic treatment.the other group will only receive routin antibiotic treatment. Demographic, clinical and lab date will be collected at baseline and at the end of 1 week of intervention initiation and will be compared bystatistical analysis with SPSS

Participants/Inclusion and exclusion criteria

Inclusion criteria:Preterm neonate with positive blood culture of late onset sepsis clinical signs of sepsis:temprature instability-respiratory disorders-cardiovascular disorders-gastrointestinal disorders
Exclusion criteria:neonate with cranial hemorrhage-maternal infection -renal disorders-neonate with tolerance to xanthine products that cause anaphylactic reaction

Intervention groups

Intervention group:Will be received Pentoxyfilin orally at a dose of 10 mg/kg every eight hours for 6 days with routin antibiotic treatment(Amikacin-Vancomycin)
Control group: will be received routin antibiotic for sepsis(Amikacin at a dose of 15-20 mg\kg-Vankomycin at a dose of 45-60 mg\kg\day divided every 6-8 hours) with supportive oxygen therapy.

Main outcome variables

Number of hospitalized days, Duration of making CRP marker negative,Need for intubation and mechanical ventilarion,Metabolic acidosis, Duration needed for oxygene therapy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180404039187N7**
Registration date: **2020-06-22, 1399/04/02**
Registration timing: **registered_while_recruiting**

Last update: **2020-06-22, 1399/04/02**
Update count: **0**

Registration date

2020-06-22, 1399/04/02

Registrant information

Name

Elnaz Shaseb

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 1337 2250

Email address

shasebe@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-20, 1399/02/01

Expected recruitment end date

2020-09-21, 1399/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The study of efficacy of Pentoxifylline in late Sepsis in preterm neonate(Trial clinical randomized)

Public title
evaluation effect of Pentoxifylline in sepsis.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Preterm neonate with positive blood culture of sepsis clinical signs of sepsis: temprature instability respiratory disorders cardiovascular disorders gastrointestinal disorders preterm neonates with late onset sepsis(having sepsis 72 hours after birth)
Exclusion criteria:
neonate with cranial hemorrhage maternal infection renal disorders neonate with tolerance to xanthine products that cause anaphylactic reaction
Age
To **259 days** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Arrangement of the randomization process: 1) Determining the volume of each block (quadruple blocks) 2) Preparing the list of the blocks and assigning a number to each of them AABB(1) ABAB(2) ABBA(3) BBAA(4) BABA(5) BAAB(6) 3) Choosing random numbers between 1 and 6 4) Defining the treatment assignment list For example: AABB(1)_BBAA(4)_ABAB(2)_BABA(5)
Blinding (investigator's opinion)
Single blinded
Blinding description
The participants (patients) are all blind during the study. At the patient's level, blindness will be done as the patients do not know in which group (control or intervention group) they are in. only The researcher has been informed and prescribes to patients according to the randomized list.
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
Research & Technology Dept, Central Building No. 2, Third Floor, Tabriz University of Medical Sciences, Golghast St, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5166614766
Approval date
2019-12-25, 1398/10/04
Ethics committee reference number
IR.TBZMED.REC.1398.996

Health conditions studied

1

Description of health condition studied
neonatal late sepsis
ICD-10 code
A41
ICD-10 code description
Other sepsis

Primary outcomes

1

Description
Number of hospitalized days
Timepoint
During the study
Method of measurement
Count the days of hospitalization

2

Description
Duration of making CRP marker negative
Timepoint
At the beginning and during the study
Method of measurement
laboratory tests

3

Description
Need for intubation and mechanical ventilarion
Timepoint
During the study
Method of measurement
Checking patient records

4

Description
Metabolic acidosis
Timepoint
During the study
Method of measurement
Laboratory test(ABG)

5

Description
Duration needed for oxygene therapy
Timepoint
During the study
Method of measurement
Counting days under oxygen therapy

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: received Pentoxyfilin orally at a dose of 10 mg/kg every eight hours for 6 day with routin antibiotic treatment(Amikacin at a dose of 15-20 mg\kg-Vankomycin at a dose of 45-60 mg\kg\day divided every 6-8 hours)
Category
Treatment - Drugs

2

Description
Control group: received routin antibiotic for sepsis(Amikacin at a dose of 15-20 mg\kg-Vankomycin at a dose of 45-60 mg\kg\day divided every 6-8 hours with supportive oxygen therapy)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra hospital
Full name of responsible person
Elnaz Shaseb
Street address
Alzahra hospital,Southern Artesh Ave.,Baghshomal Crossroad
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Abolghasem Jouyban
Street address
No. 2,Central Building,Tabriz University of Medical Sciences, Golgasht Ave,.Azadi Ave.
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Tabriz University of Medical Sciences
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available