Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 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
City
Tabriz
Province
East Azarbaijan
Postal code
5138663134
Phone
+98 41 3553 1619
Email
alzahra@mui.ac.ir

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.
City
Tabriz
Province
East Azarbaijan
Postal code
5166614766
Phone
+98 41 3337 2250
Email
Jouyban@tbzmed.ac.ir
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
Street address
Faculty of Pharmacy, Tabriz university of Medical Science, Golgasht Ave.,Azadi Ave.

City
Tabriz
Province
East Azarbaijan
Postal code
5166614766
Phone
0098 144933344198
Email
Elnaz_shaseb_64@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Elnaz Shaseb
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
Faculty of Pharmacy, Tabriz university of Medical Science, Golgasht Ave.,Azadi Ave.
City
Tabriz
Province
East Azarbaijan
Postal code
5166614766
Phone
0098 144933344198
Email
Elnaz_shaseb_64@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Donya Behzadimohammadi
Position
Student
Latest degree
Medical doctor
Other areas of specialty/work
Medical Pharmacy
Street address
Faculty of Pharmacy,Tabriz university of Medical Science, Golgasht Ave,.Azadi AVE.
City
Tabriz
Province
East Azarbaijan
Postal code
5166614766
Phone
+98 41 3553 2834
Email
donya_b_1372@yahoo.com

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