Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigation of the effect of exosomes extracted from the umbilical cord in the treatment of bronchopulmonary dysplasia in premature infants

Protocol summary

Study aim
Comparison of pulmonary function and severity of BPD at 3 months in both study groups.

Design
This is a randomized, double-blind, parallel-group, controlled phase 2 clinical trial on 30 patients. The R software was used for randomization.

Settings and conduct
In this study, two groups of 15 premature infants with moderate to severe bronchopulmonary dysplasia will be randomly selected who were hospitalized between the years 2025 to 2026 at Al-Zahra Hospital in Tabriz - neonatal intensive care unit. Researchers, evaluators, and patients will be blinded to the intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Premature infants born with a gestational age less than or equal to 32 weeks and 28 weeks or more, high-risk infants for moderate to severe bronchopulmonary dysplasia, and infants who are intubated or receiving treatment with an oxygen concentration fraction higher than 30%. Exclusion criteria: Major congenital anomalies, including neurological anomalies (such as anencephaly and similar anomalies), liver, kidney, cardiovascular anomalies (except for patent ductus arteriosus, PDA), any infections including pneumonia, sepsis, or shock, severe intraventricular hemorrhage.

Intervention groups
In the case group, premature infants with moderate to severe bronchopulmonary dysplasia will be admitted and will receive exosomes extracted from the umbilical cord through a laryngeal mask. Infants in the control group will receive routine ward treatments and conventional respiratory care.

Main outcome variables
Pulmonary function and severity of BPD at 3 months; Mechanical ventilation cases and complications related to BPD; Duration of oxygen requirement; Duration of hospitalization; Mortality

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20241122063802N5**
Registration date: **2025-10-22, 1404/07/30**
Registration timing: **prospective**

Last update: **2025-10-22, 1404/07/30**
Update count: **0**

Registration date
2025-10-22, 1404/07/30

Registrant information
Name
Reza Sattarpour
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
recruiting
Funding source

Expected recruitment start date
2025-11-22, 1404/09/01
Expected recruitment end date
2026-11-22, 1405/09/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

Investigation of the effect of exosomes extracted from the umbilical cord in the treatment of bronchopulmonary dysplasia in premature infants

Public title

Investigation of the effect of exosomes extracted from the umbilical cord in the treatment of bronchopulmonary dysplasia in premature infants

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Premature neonates born with a gestational age ≤32 weeks and 28 weeks or above High-risk neonate for moderate to severe BPD Age of study entry after day 14th of life Neonate is intubated or receiving treatment with FiO2 greater than 30% Obtaining voluntary informed consent

Exclusion criteria:

Having a major congenital anomaly, including neurological anomalies (such as anencephaly and similar anomalies), liver, kidney, or cardiovascular anomalies (except patent ductus arteriosus, PDA). Having a known genetic syndrome. Having CRP > 30 mg/l or any infection including pneumonia, sepsis, or shock. Having severe (Grade >3) intraventricular hemorrhage (IVH) previously. Being infected with HIV or CMV. Currently participating in any other interventional clinical trial.

Age

From **14 days** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

The selection of participants will be done randomly in a 1:1 ratio to receive either exosome treatment or standard treatment alone, using computer-generated random blocks with R software.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, double blinding is performed by ensuring that neither the infants' parents nor the medical staff and outcome assessors are aware of the type of treatment administered (exosome or standard treatment), thereby preventing bias.

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

Central Building of Tabriz University of Medical Sciences, Azadi Ave., Golgasht St., Tabriz, Iran

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2025-10-06, 1404/07/14

Ethics committee reference number

IR.TBZMED.REC.1404.511

Health conditions studied

1

Description of health condition studied

Bronchopulmonary dysplasia

ICD-10 code

P27.1

ICD-10 code description

Bronchopulmonary dysplasia originating in the perinatal period

Primary outcomes

1

Description

Pulmonary function and severity of BPD at 3 months

Timepoint

Beginning and end of the study

Method of measurement

NIH BPD severity scale

2

Description

Mechanical ventilation cases and complications related to BPD

Timepoint

Beginning and end of the study

Method of measurement

Questionnaire filled out during the study

Secondary outcomes

1

Description
Duration of oxygen requirement
Timepoint
Beginning and end of the study
Method of measurement
Questionnaire filled out during the study

2

Description
Duration of hospitalization
Timepoint
Beginning and end of the study
Method of measurement
Questionnaire filled out during the study

3

Description
Mortality
Timepoint
Beginning and end of the study
Method of measurement
Questionnaire filled out during the study

Intervention groups

1

Description
Intervention group: In this group, premature infants with moderate to severe bronchopulmonary dysplasia will be enrolled after obtaining parental consent. This study will use exosomes produced by the Middle East Gene and cell Therapy Company. Collection of human umbilical cord samples will be carried out by obtaining fresh umbilical cords from healthy, term pregnancies, ensuring that informed consent and approval from the ethics committee have been obtained. Processing of these samples will be done within six hours after collection to preserve the integrity of the exosomes. The dose of exosomes is considered to be 10 × 10^8 particles per kilogram of body weight. The administration method is via intratracheal injection through a laryngeal mask over a period of 3 minutes. The number of treatment sessions is twice a week for four weeks. The maximum volume of fluid used will be 5 cc per kilogram of weight to prevent side effects caused by reduced respiratory levels. At the same time, this group will receive standard supportive treatments related to BPD.
Category
Treatment - Drugs

2

Description
Control group: This group will receive routine ward treatment, with the routine treatment protocol similar to the exosome treatment group. At the same time, this group will receive standard supportive treatments related to BPD.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra Women's Hospital Tabriz, Neonatal Intensive Care Unit (NICU)
Full name of responsible person
Manizheh Mostafa Gharehbaghi
Street address
Al-Zahra Educational and Treatment Center, Baghshamal Intersection, South Army Street
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alzahrahospital@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Khosro Adibkia
Street address
Central Building of Tabriz University of Medical Sciences, Azadi Ave., Golgasht St., Tabriz, Iran
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Email
research-vice@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

Reza Sattarpour

Position

Research Assisstant

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

Reza Sattarpour

Position

Research Assisstant

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

Reza Sattarpour

Position

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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Due to the use of hospital data and the confidentiality policies of the university and hospital, public release of the data will be avoided. However, researchers may contact the responsible person to request access to the data.

Study Protocol

Yes - There is 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

Yes - There is 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

Title and more details about the data/document

Due to the use of hospital data and the confidentiality policies of the university and hospital, public release of the data will be avoided. However, researchers may contact the responsible person to request access to the data.

When the data will become available and for how

long

Due to the use of hospital data and the confidentiality policies of the university and hospital, public release of the data will be avoided. However, researchers may contact the responsible person to request access to the data.

To whom data/document is available

Due to the use of hospital data and the confidentiality policies of the university and hospital, public release of the data will be avoided. However, researchers may contact the responsible person to request access to the data.

Under which criteria data/document could be used

Hospitals and affiliated institutions have policies to maintain confidentiality and secure data access, often implementing role-based access control (RBAC) to limit who can view or use patient information based on their role and necessity.

From where data/document is obtainable

For research purposes, contact is typically made with the hospital's research office or ethics committee to obtain necessary approvals and ensure compliance with confidentiality agreements.

What processes are involved for a request to access data/document

Submission of a Written Request: The requester must submit a formal written application specifying the data or documents needed and the intended use. Patient Consent: For access to identifiable medical records, written consent from the patient (or legal guardian) is required unless exceptions apply (e.g., emergencies, legal orders). Review and Approval: The hospital's Medical Records Department and/or Ethics Committee review the request to ensure compliance with privacy policies and legal regulations. Data Preparation: Upon approval, the requested data are prepared, which may include de-identification or anonymization if for research purposes. Confidentiality Agreement: The requester may be required to sign a confidentiality agreement or data use agreement to protect patient privacy. Data Delivery: The data or documents are provided securely, often with a certification (e.g., "Certified True Copy") if official copies are requested.

Comments