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Epidemiological study of neonatal respiratory failure

Submission date	Recruitment status	[_] Prospectively registered
10/09/2022	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/10/2022	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
08/07/2024	Respiratory	

Plain English summary of protocol

Background and study aims
This study will consider past events (retrospectively) to investigate the morbidity, mortality, and respiratory support treatment status of neonatal respiratory failure (NRF) in the neonatal intensive care unit (NICU) in Jiangsu Province, China.

Who can participate?
Infants with respiratory failure diagnosed in the NICU of 30 hospitals in Jiangsu Province

What does the study involve?
A multi-center investigational platform and database were constructed to look at the incidence, distribution, and control of disease for NRF in Jiangsu Province. A data collection form was set up in the network platform, including the basic information of the children, the NICU status form, the respiratory treatment form, the drug use form, the hospitalization status, and the prognosis form. Retrospective data collection was conducted in cases of respiratory failure in the NICU. The data included the demographic characteristics of the children, the mother’s prenatal disease, perinatal conditions, disease diagnosis, and clinical treatment of the respiratory system, mortality score, and prognosis of children. The NICUs of 30 tertiary A hospitals in Jiangsu Province participated in the survey and were all equipped with professional neonatologists who had undergone training as data entry personnel. Each branch center set up a quality control specialist to check the data. This study was approved by the Medical Ethics Committee of the Children's Hospital of Nanjing Medical University, and informed consent was obtained from the guardians of the children.

What are the possible benefits and risks of participating?
There are no direct benefits or risks involved in taking part in this study.

Where is the study run from?
Nanjing Medical University (China)

When is the study starting and how long is it expected to run for?
March 2020 to March 2023

Who is funding the study?
Children’s Hospital of Nanjing Medical University (China)

Who is the main contact?
Dr Keyu Lu (China)
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Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Morbidity and mortality of neonatal respiratory failure in the Jiangsu province of China

Acronym
MMNRF

Study objectives

This study retrospectively investigated the morbidity, mortality, and respiratory support treatment status of neonatal respiratory failure (NRF) in the neonatal intensive care unit (NICU) in Jiangsu Province, China.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/04/2020, Children's Hospital of Nanjing Medical University Ethics Committee (72 Guangzhou Road, 210008 Nanjing, Jiangsu, China; +86 (0)83117281; nanjingnicu@163.com), ref: 202004037-1

Study design
Cross-sectional cohort study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Treatment of neonates with respiratory failure

Interventions
A multicenter clinical epidemiological investigation platform and clinical database were constructed for neonatal respiratory failure (NRF) in Jiangsu Province. A data collection form was set up in the network platform, including the basic information form of children, the NICU status form, the respiratory treatment form, the drug use form, the hospitalization status, and the prognosis form. Retrospective data collection was conducted in cases of respiratory failure in the NICU. The data included the demographic characteristics of the children, the mother's prenatal disease, perinatal conditions, disease diagnosis, and clinical treatment of the respiratory system (mainly respiratory treatments such as surfactants, assisted ventilation, inhaled NO, etc.), SNAPE-II score, and prognosis of children. The NICUs of 30 tertiary A hospitals in Jiangsu Province participated in the survey and were all equipped with professional neonatologists who had undergone homogeneous training as data entry personnel. Each branch center set up a quality control specialist to check the data.

The study was based on whether the final outcome of the child died as the cut-off point. The study used multivariate logistic regression analysis to find high-risk factors for neonatal respiratory failure death.

Intervention Type
Other

Primary outcome measure
Comorbidities and mortality of neonates with respiratory failure assessed by measuring the requirement for respiratory support and the use of surfactants. Ventilator parameters required by patients in the study (eg PIP, PEEP, FiO2, RR, Ti) and alveolar surfactant (use time, dose, frequency, route of use) will be recorded in the respiratory treatment form at the end of the study observation

Secondary outcome measures
Multiple regression analysis of the risk of death measured using a data collection form set up in the network platform, including a basic information form, a NICU status form, a respiratory treatment form, a drug-use form, hospitalization status, and a prognosis form at the end of the study observation

Overall study start date
01/03/2020

Completion date
01/03/2023

Eligibility

Key inclusion criteria
Children aged 28 days old and under and in need of receiving auxiliary ventilation (including mechanical ventilation and non-invasive ventilation)

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
6000

Total final enrolment
1436

Key exclusion criteria
Children who needed assisted ventilation due to respiratory depression caused by surgery or the application of sedative drugs

Date of first enrolment
01/05/2020

Date of final enrolment
01/05/2023

Locations

Countries of recruitment
China

Study participating centre
Children’s Hospital of Nanjing Medical University
Guangzhou road 72
Nanjing
China
210009

Study participating centre
Changzhou Children’s Hospital
No. 468
Middle Yanling Road
Tianning District
Changzhou
China
213002

Sponsor information

Organisation
Nanjing Medical University

Sponsor details
Department of Newborn Infants
Children’s Hospital of Nanjing Medical University
72 Guangzhou Road
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210008
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Sponsor type
University/education

Website

https://www.njch.com.cn

ROR
https://ror.org/059gcgy73

Funder(s)

Funder type
University/education

Funder Name
Nanjing Medical University

Alternative Name(s)
, NMU

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
China

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal; BMC Pediatrics

Intention to publish date
30/06/2023

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		03/07/2024	08/07/2024	Yes	No