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A clinical trial to study the risk factors of bronchopulmonary dysplasia in Chinese preterm infants

Submission date
18/02/2020

Recruitment status
No longer recruiting

Registration date
25/02/2020

Overall study status
Completed

Last Edited
04/04/2024

Condition category
Neonatal Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Bronchopulmonary dysplasia (BPD) remains one of the principal causes of death and respiratory problems in very premature infants (<32 weeks of gestation) both during hospitalization and in the first years of life. The aim of this study is to explore the risk factors for BPD in the population of Chinese very preterm infants.

Who can participate?
Preterm infants admitted within 72 hours after birth, gestational age <32 weeks and respiratory distress score ≥5

What does the study involve?
This study will collect data from 39 NICUs of tertiary hospitals in China, including obstetric conditions, relevant records during delivery, and materials of respiratory support, drug application, infection status, circulation management and nutritional fluid after birth. The primary outcomes of this study are early death (between 14 days of postnatal age and 36 weeks PMA) and BPD (36 weeks PMA), the secondary outcomes are the grade and severity of BPD.

What are the possible benefits and risks of participating?
There are no direct benefits or risks of taking part in this study, but it is hoped that the study will inform researchers examine the risk factors of BPD, and provide the evidence-based support for follow-up research.

Where is the study run from?
The Children's Hospital Zhejiang University School of Medicine (China)

When is the study starting and how long is it expected to run for?
January 2020 to December 2021

Who is funding the study?
China National Clinical Research Center for Child Health/China National Children's Regional Medical Center

Who is the main contact?
Dr Zheng Chen
chenz@zju.edu.cn

Study website
https://www.ncrcch.org/

Contact information

Type(s)
Scientific

Contact name
Dr Zheng Chen

Contact details
Principal Investigator
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China
310052
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chenz@zju.edu.cn

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2019-IRB-164 1.0; ChiCTR2000030125

Study information

Scientific Title
Risk factors for bronchopulmonary dysplasia in preterm infants - a multicenter prospective cohort study in China

Acronym
RFBPD-CHN

Study objectives
This study will explore the risk factors of BPD according to the 2018 NICHD definition, and provide the evidence-based support for follow-up research.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/12/2019, medical ethics committee of The Children's Hospital Zhejiang University School of Medicine (No. 3333 Binsheng Road, HangZhou, Zhejiang, China, 310052; +86 (0)571 86670072; zuchiec@163.com), ref: 2019-IRB-164

Study design
Multicenter prospective cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Screening

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

Health condition(s) or problem(s) studied
Bronchopulmonary dysplasia in preterm infants

Interventions
This study will collect the data from 39 NICU of tertiary hospitals in China, including obstetric conditions, relevant records during delivery, and materials of respiratory support, drug application, infection status, circulation management and nutritional fluid after birth. The total duration of observation is from birth to 36 weeks postmenstrual age (PMA) after birth. There is no follow-up after endpoint of the study.

Intervention Type
Other

Primary outcome measure
1. Early death (between 14 days of postnatal age and 36 weeks PMA) measured using data from medical records, defined as owing to persistent parenchymal lung disease and respiratory failure that cannot be attributable to other neonatal morbidities (eg, necrotizing enterocolitis, intraventricular hemorrhage, redirection of care, episodes of sepsis, etc)
2. BPD at 36 weeks PMA measured using data from medical records, defined as a premature

infant (<32 weeks' gestational age) with persistent parenchymal lung disease confirmed by radiography, and at 36 weeks PMA requires oxygen for ≥3 consecutive days to maintain arterial oxygen saturation in the 90%–95% range

The incidence of early death and BPD are calculated by the corresponding rate for the total study population in the database

Secondary outcome measures
The grade and severity of BPD according to the definition of 2018 NICHD BPD workshop at 36 weeks PMA

Overall study start date
01/01/2020

Completion date
31/12/2021

Eligibility

Key inclusion criteria
Preterm infants admitted within 72 hours after birth, gestational age <32 weeks and respiratory distress score ≥5

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
This study will recruit more than 1000 patients

Key exclusion criteria
Congenital malformations such as complex congenital heart disease, diaphragmatic hernia, anomalies of digestive tract/kidney, and genetic metabolic disorders

Date of first enrolment
01/03/2020

Date of final enrolment
28/02/2021

Locations

Countries of recruitment
China

Study participating centre
The Children’s Hospital, Zhejiang University School of Medicine
No. 3333 Binsheng Road
Hangzhou
China
310052

Study participating centre
Children’s Hospital of Chongqing Medical University
No. 136 Zhongshan 2 Road
Chongqing
China
400014

Study participating centre
Women's Hospital School Of Medicine Zhejiang University
No. 1 Xueshi Road
Hangzhou
China
310006

Study participating centre
Shanghai children‘s hospital, Shanghai Jiao Tong University School of Medicine
No. 355 Luding Road
Shanghai
China
200062

Study participating centre
The Affiliated Obstetrics and Gynecology Hospital of Nanjing Medical University
No. 123 Tianfei lane, Mochou Road
Nanjing
China
210011

Study participating centre
Ningbo Women and Children's hospital
No. 339 Liuding Road
Ningbo

China
315012

Study participating centre
Shenzhen Maternity & Child Healthcare Hospital
No. 2004 Hongli Road
Shenzhen
China
518028

Study participating centre
First Hospital of Jilin University
No. 71 Xinmin Street
Changchun
China
130021

Study participating centre
Bethune International Peace Hospital of PLA
No. 398 Zhongshan West Road
Shijiazhuang
China
050082

Study participating centre
5th Medical Center of Chinese PLA General of Hospita
No. 100 West 4th Ring Middle Road
Beijing
China
100039

Study participating centre
The First Hospital of Tsinghua University
No. 6 Yijiefang Jiuxianqiao
Beijing
China
100016

Study participating centre

Peking University Third hospital
No. 49 Huayuan North Road
Beijing
China
100191

Study participating centre
Quanzhou Women's and Children's Hospital
No. 700 Fengze Street
Quzhou
China
362000

Study participating centre
Chongqing Health Center for Women and Children
No. 120 Longshan Road, Yubei District
Chongqing
China
401147

Study participating centre
Chengdu Women's & Children's Central Hospital
No. 1617 Riyue Avenue
Chengdu
China
610074

Study participating centre
Guizhou Maternity and Child Health Care Hospital
No. 63 Ruijin South Road
Guiyang
China
550003

Study participating centre
The First Affiliated Hospital of Guangxi Medical University
No. 6 Shuangyong Road
Nanning
China
530021

Study participating centre
The Second Affiliated Hospital of Guangxi Medical University
No. 166 Daxuedong Road
Nanning
China
530007

Study participating centre
The Maternal & Child Health Hospital of Guangxi Zhuang Autonomous Region
No. 59 Xaingzhu Avenue
Nanning
China
530002

Study participating centre
First Affiliated Hospital of Kunming Medical University
No. 295 Xichang Road
Kunming
China
650032

Study participating centre
The Second Affiliated Hospital of Kunming Medical University
No. 374 Dianmian Avenue
Kunming
China
650101

Study participating centre
Kunming Children's Hospital
No. 288 Qianxing Road
Kunming
China
650228

Study participating centre
The First Affiliated Hospital of Zhengzhou University
No. 1 Jianshe East Road
Zhengzhou

China
450052

Study participating centre
Henan Children's Hospital
No. 33 Longhu Waihuan East Road
Zhengzhou
China
450018

Study participating centre
Henan Provincial People's Hospital
No.7 Weiwu Road
Zhengzhou
China
450003

Study participating centre
Shaanxi Provincial People's Hospital
No. 256 Youyi West Road
Xian
China
710068

Study participating centre
The First Affiliated Hospital of Xinjiang Medical University
No. 137 Liyushan South Road
Urumqi
China
830054

Study participating centre
The People's Hospital of Xinjiang Uygur Autonomous Region
No. 91 Tianchi Road
Urumqi
China
830001

Study participating centre

Qinghai Provincial Women & Children's hospital
No. 15 Gonghe South Road
Xining
China
810007

Study participating centre
Inner Mongolia People's Hospital
No. 20 Zhaowuda Road
Hohhot
China
010017

Study participating centre
Gansu Provincial Maternity and Child-care Hospital
No.143 Qilihe North Street
Lanzhou
China
730050

Study participating centre
Xuzhou Children's Hospital
No. 18 Sudi North Road
Xuzhou
China
221002

Study participating centre
Yulin Maternity & Child Healthcare Hospital
No. 290 Qingning Road
Yulin
China
537000

Study participating centre
Chinese Traditional Medicine Affiliated Hospital of Southwest Medical University
No. 182 Chunhui Road
Luzhou
China
646600

Study participating centre
Qujing Maternity & Child Healthcare Hospital
No. 371 Liaokuo South Road
Qujing
China
655000

Study participating centre
Taian Maternal and Child Health Hospital
No. 386 Longtai Road
Taian
China
271000

Study participating centre
The Second Affiliated Hospital of Ningxia Medical University
No. 2 Liqun South Street
Yinchuan
China
750001

Study participating centre
Mianyang Central Hospital
No. 12 Changjia Lane, Jingzhong Street
Mianyang
China
621000

Study participating centre
Chongqing Three Gorges Central Hospital
No. 165 Xincheng Road
Chongqing
China
404000

Sponsor information

Organisation

Children's Hospital of Zhejiang University

Sponsor details
3333 Binsheng Road
Hangzhou
China
310052
+86 (0)571 86670083
chenz@zju.edu.cn

Sponsor type
Hospital/treatment centre

Website
http://www.zjuch.cn

ROR
https://ror.org/025fyfd20

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
China National Clinical Research Center for Child Health/ China National Children’s Regional Medical Center

Results and Publications

Publication and dissemination plan
Findings will be published in relevant medical journals, at conferences and to members of the public via the website of The Children's Hospital Zhejiang University School of Medicine.

Intention to publish date
31/12/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Ms Yusang Dong (yusang_dong@zju.edu.cn). All information of the study will be collected on data forms, with data being entered into the Resman research manager database of ChiCTR for subsequent analysis. CNCRCCH (China National Clinical Research Center for Child Health) will save all the study data and complete data analysis. The data will be available when the recruitment start and upload within 3 months later. The data will be available for 3 years since then. Only members of this study will have permission to access the database.

The investigators of other participating hospitals will be authorized to share the summary of the data and analyze the results. Data access will comply with privacy regulations, and all data will be kept by a specialist to protect the patients' privacy. To ensure ethical standards are met, the researchers will obtain informed consent from each participating parent before enrollment and will respect the parents' decision to join or leave the study at any time. All data will be identified, and the researchers will use patients' ID numbers instead of names when summarizing data. Qualitative and quantitative data will be collected during the study; nominal, ordinal, interval may also be used during the study. The study is a multi-center clinical study which will include analytics-descriptive predictive analytics and so on.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			06/03/2020	No	No
Results article		03/04/2024	04/04/2024	Yes	No