

**Noninvasive Ventilation for Preterm Neonates With
Respiratory Distress Syndrome: a Multi-center Randomized
Controlled Trial**

(NCT03099694)

13 July 2017

Solid PDF/A Express
<http://www.SolidDocuments.com/>



Informed Consent Form

Dear Madam/Sir:

We are considering inviting you and your baby to participate in a multicenter, randomized, controlled study: Noninvasive high frequency oscillatory ventilation (NHFOV) vs. Nasal continuous positive airway pressure (NCPAP) as a Primary Treatment to Neonatal Respiratory Distress Syndrome (Clinicalstudies.gov Identifier: NCT03099694). Before agreeing to participate in the study, it is important that you understand the specific content of the study. Please read this document carefully and ask questions. This study has been approved by the Ethics Committee of Daping Hospital, Study Institute of Surgery, Third Military Medical University. Whether you and your baby participate in this study depends entirely on your personal wishes.

1. The purpose of the study

The aim of this study is to compare the efficacy and safety of NHFOV and NCPAP in the treatment of respiratory distress syndrome (RDS) in infants between 26⁺⁰ and 33⁺⁶ weeks gestational age (GA) when used as a primary noninvasive ventilation (NIV) mode.

2. An explanation of the study

RDS due to surfactant deficiency is the leading cause of respiratory failure in preterm infants. NCPAP has become the gold strategy for the

early respiratory management of RDS in preterm infants. However, NCPAP has a higher failure rate in premature infants with moderate-severe RDS. NHFOV provides the advantages of high-frequency ventilation (no need for synchronisation, high efficacy in removing CO₂) and NCPAP (non-invasive interface, increase in functional residual capacity allowing oxygenation to improve). There is enough clinical expertise demonstrating that NHFOV may be tried in premature infants with moderate-severe RDS, in whom CPAP or conventional non-invasive ventilation have failed. Nonetheless, there are no clear data about its clinical usefulness and there is a need for randomised controlled studies.

3. The number of subjects and duration of patient participation

We plan to recruit at least 300 premature infants with RDS in the study. The total time of this study is estimated to be 18 months, and The participation time is estimated to be 24 months.

4. The procedures to be followed by patients

Preterm infants are eligible to the study if they present with RDS diagnosed by clinical manifestations (tachypnea, nasal flaring and or grunting) and the typical X-ray picture of RDS. They are randomly assigned to one of the treatment groups to receive NCPAP or NHFOV. For all the groups, if the FiO₂ requirement is persistently higher than 0.40 per target SpO₂ 89-94% after starting the respiratory support, newborns

receive Surfactant by "INSURE" technique, involving endotracheal intubation by direct laryngoscopic vision, endotracheal administration of surfactant (Curosurf, Chiesi Pharmaceuticals, Parma, Italy) 200 mg/kg and finally extubation. Criteria for intubation and mechanical ventilation were the following: (1) severe respiratory acidosis ($P_aCO_2 > 65$ mmHg with $pH < 7.20$); (2) severe apnea and bradycardia (defined as recurrent apnea with > 3 episodes per hour associated with heart rate < 100 /min, a single episode of apnea that requires bag and mask ventilation); (3) hypoxia ($FiO_2 > 0.5$ with $PaO_2 < 50$ mmHg), severe respiratory distress; (4) pulmonary hemorrhage; (5) pneumothorax; (6) cardiopulmonary arrest needing chest compressions. The criteria for weaning noninvasive respiratory will be: (1) minimal or no signs of respiratory distress (RES Silverman score ≤ 5); (2) NHFOV MAP or NCPAP pressure ≤ 6 cmH₂O and (3) $FiO_2 < 0.25$ to achieve target SpO_2 . For all the newborns enrolled in the study, capillary or venous blood gas is checked every 6-12 hours, a cerebral and cardiac ultrasound screening is performed within 24 hrs. Further controls follow the routine of the ward. In general routine medical care and nursing will not be changed because of the study, out of the trial intervention; the clinical care will be identical in the two study arms. No additional blood samples are required for this study.

If you allow your baby to participate in this study, you need to sign this informed consent form after you understand the content of the whole study and your questions have been answered satisfactorily.

Investigators will begin to arrange for relevant inspection and study operations. These checks and study operations will help determine whether your baby is suitable for this study. This stage is "pre-study stage". If the investigator decides that your baby have not met the inclusion, your baby will not be allowed to participate in this study. Investigators will advise your baby to receive alternative treatment.

5. The potential discomforts and risks

Participants in this study may face complications of noninvasive ventilation: vomiting, feeding intolerance, abdominal distention, pneumothorax, necrotizing enterocolitis, intracranial hemorrhage, nasal trauma, pain, etc

6. The expected benefits

Your baby will be exempt from the cost of treatment and may have the opportunity to receive more advanced non-invasive ventilation mode to reduce the risk of invasive mechanical ventilation.

7. The alternative treatments and procedures that might also be beneficial

Your baby does not have to participate in this study to treat RDS. You can choose other treatments for your baby

8. The compensation or medical treatments available if injury occurs

If your baby suffers from study-related damage in the course of participating in the study, we will provide you with emergency treatment free of charge. Damage compensation during the study period will be implemented in accordance with the relevant laws of China

9. The protection of confidentiality and privacy

Investigators are responsible for following applicable data protection regulations to process data. However, such information can be accessed by ethics committees and inspections by administrative departments. The results may be published in medical journals/conferences, but personal information about you and your baby will not be made public.

Your baby's health information is protected by relevant Chinese laws. After signing this informed consent, you agree to collect, use and share your baby's health information data with investigators. Your baby's name is abbreviated and a code assigned to the study data is now available to investigators. Your authorization to use your baby's health information will remain valid until the end of the study and the results of the study are available. At the end of the study and after the results are obtained, we will delete your personal information and your baby's information from the study records.

10. The participation is voluntary

Participation in this study is entirely out of your personal desire to return

your baby. Your baby can choose not to participate in this study, your baby can also withdraw at any time, any treatment and rights of your baby will not be affected, and will not be discriminated against by doctors.

11. Who to contact with questions about the study

Before you sign this agreement, all members of the study will answer all your questions. If you still have questions, suggestions or comments after signing the consent, you can also communicate with the investigators. You can keep abreast of the relevant information and study progress of this study.

Investigators and telephone numbers:

A statement that participation is voluntary

The investigator concerned has orally informed me of the relevant information in this study, and I have read the above written information.

I had ample opportunity to discuss and ask questions about the above study.

I agree to participate in this study and understand that my participation in this study is entirely voluntary.

I understand that I can withdraw from the study at any time, and that my withdrawal will not affect my future medical treatment.

By signing this informed consent, I agree that my personal information

data, including my medical information data, will be used in the manner described above.

I know I will get a copy of this informed consent.

Parent/Guardian _____

Date _____

Physician _____

Date _____

Solid PDF/A Express
<http://www.SolidDocuments.com/>

