# CLINICAL STUDY REPORT

A Multinational, Multicenter, Masked, Randomized Parallel Group, Controlled Study to Assess the Safety and Efficacy of Lucinactant for Inhalation versus nCPAP alone in Preterm Neonates 26 to 32 Weeks Gestational Age with Respiratory Distress Syndrome

**Protocol Number: 03-CL-1702**
**Study Phase: 2b**

**Version: 1.1**
**Date of Report: 27 October 2021**

Study Initiation Date: 18 April 2020
Study Completion Date: 19 January 2021

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| **Investigational Product:** | AEROSURF® (lucinactant for inhalation) |
| **IND Number:** | 119438 |
| **ClinicalTrials.gov No.:** | NCT04264156 |
| **EudraCT No.:** | 2018-000106-32 |
| **Indication:** | Respiratory Distress Syndrome |


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| **Sponsor:** | Windtree Therapeutics, Inc. |
| **Sponsor Contact:** | Steven G. Simonson, MD, MHS |
| **Sponsor's Medical Officer:** | Steven G. Simonson, MD, MHS<br>Senior Vice President and Chief Medical Officer |
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See Appendix 16.1.4 for a complete list of all investigators and study centers.

## 2. SYNOPSIS

| **Name of Sponsor/Company:** | **Name of Finished Product:** | **Name of Active Ingredients:** |
|---|---|---|
| Windtree Therapeutics, Inc.<br>2600 Kelly Road<br>Suite 100<br>Warrington, PA 18976<br>USA | AEROSURF® (lucinactant for inhalation)<br>Lucinactant 30 mg/ml total phospholipids (reconstituted) | Dipalmitoyl-phosphatidylcholine (DPPC), palmitoyloleoyl-phosphatidylglycerol sodium salt (POPG, Na), palmitic acid (PA), and sinapultide ($KL_4$-peptide) |

**Title of Study:**

A Multinational, Multicenter, Masked, Randomized Parallel Group, Controlled Study to Assess the Safety and Efficacy of Lucinactant for Inhalation versus nCPAP alone in Preterm Neonates 26 to 32 Weeks Gestational Age with Respiratory Distress Syndrome

**Investigators and Study Centers:**

A total of 4 investigators from Poland received central ethics committee (EC) and competent authority approval, of which 3 received sponsor approval for participation in this study. A total of 3 investigators enrolled subjects. The names of the investigators, addresses of the study centers, and copies of the investigators' curricula vitae are provided in Appendix 16.1.4.

**Publication (reference):**

None

| **Study Period:** | **Phase of Development:** |
|---|---|
| 18 April 2020 – 19 January 2021 | 2b |

**Objectives:**

The objectives of this study were to evaluate the safety and efficacy of lucinactant for inhalation (AEROSURF®) delivered by the next generation AEROSURF delivery system (ADS) device in conjunction with nCPAP, in comparison to nasal continuous positive airway pressure (nCPAP) alone, in preterm neonates with respiratory distress syndrome (RDS), as assessed by the incidence of and time to respiratory failure due to RDS in the first 72 hours and through 28 days of life, oxygen saturation and use of supplemental oxygen, all-cause mortality through 28 days of life, the incidence of bronchopulmonary dysplasia (BPD) at 36 weeks post-menstrual age (PMA), and the duration of mechanical ventilation. In addition, this study will evaluate the device performance and the ability to administer up to 3 lucinactant for inhalation repeat treatments.

**Methodology:**

This study was planned as a multinational, multicenter, double-blind (masked), parallel group, randomized, controlled study to investigate the safety and efficacy of lucinactant for inhalation (in conjunction with nCPAP) compared to nCPAP alone. The study design included 2 parallel treatment groups (lucinactant for inhalation and nCPAP only) in preterm neonates 26 to 32 completed weeks PMA with RDS who are within the first 6 hours after birth, who had successful implementation of non-invasive mode of oxygen support (such as nCPAP, bilevel positive airway pressure[BiPAP], or oxyhood) within 30 minutes of birth, and who are candidates for surfactant replacement therapy (SRT; study nCPAP is strongly recommended as the initial mode of support). There were 2 phases defined in the study: a primary phase through 36 weeks PMA and a longer-term follow-up phase through 12 months corrected age. Data was analyzed and reported for the primary phase only; the study was terminated prior to any subjects reaching the 12-month follow-up phase timepoint.

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Before study enrollment, legally authorized representatives provided a signed informed consent form (ICF) for each potential subject. Qualification for study enrollment was established after informed consent has been provided and after confirmation that the subject has met all of the inclusion criteria and none of the exclusion criteria. The clinical criteria for enrollment could have been met prior to informed consent being obtained; however, no study-specific procedures that were not part of the usual standard care of the subject at the institution were performed until the informed consent had been provided by a legally authorized representative of the subject.

Inclusion criteria to be met within the first 6 hours after birth included respiratory insufficiency with a requirement for nCPAP of 5 to 7 $cmH_2O$ and an $FiO_2 \geq 0.25$ to $\leq 0.35$ to maintain oxygen saturation as measured by pulse oximetry ($SpO_2$) of 90% to 95% for at least 15 minutes. As soon as study qualification had been confirmed and the informed consent signed, subjects were immediately randomized (in a 1:1 ratio) to 1 of the 2 treatment groups (active or control). Subjects were enrolled by strata: 26 to 28 completed weeks PMA and 29 to 32 completed weeks PMA. Based upon the sizes of the patient populations and the prevalence of RDS in these populations, it was expected that approximately 10-15% of subjects would be 26 to 28 completed weeks PMA; however, stratification is being used to ensure balance of randomization at study sites and to ensure balance within each stratum.

In order to ensure correct functioning of the ADS and to reinforce study treatment procedures, the first 2 subjects at each site were dosed open-label on active study treatment (160 mg TPL/kg lucinactant for inhalation followed by 80 mg TPL/kg repeat treatments). All procedures for treatments and repeat treatments were followed as was done for all other subjects.

Study therapy (lucinactant for inhalation or sham/control) was to be initiated as soon as possible after randomization. Subjects for both active and sham treatments were connected to the same setup (using the study nCPAP and study airway connector). Following completion of the setup, subjects stabilized for at least 15 minutes. The start time for active treatment was the time at which the subject is connected to the ADS. The sham treatment simulated a connection to the ADS. Thus, the start time for sham treatment (treatment initiation) was the time at which this simulated connection occurred; the stop time was 110 minutes later (to account for an approximate 10 minutes to switch the syringe and cartridge in the active treatment group).

Subjects were eligible to receive up to 3 repeat study treatments (active or sham) to which they were assigned; however, the dose of the active treatment for repeat treatments was 80 mg TPL/kg. Repeat treatments were given as soon as possible, but no sooner than 20 minutes from completion of the previous treatment, up to 36 hours after randomization if the subject met repeat treatment criteria, unless it was unsafe to do so in the judgment of the PI. Subjects randomized to the control group were continued on nCPAP alone but were to receive repeated sham treatment to maintain study masking. Details on the ADS are outlined in Section 9.4.1.2.

Treatment assignments, outside the first 2 open-label subjects who received active study treatment, were masked from the PI; clinical and study staff (eg, site coordinator, bedside nurse); sponsor, as applicable; and subject's parents/legal guardians. All enrolled subjects received study treatment in a NICU, a specialized care center staffed by neonatologists, nurses, and respiratory therapists who are experienced in the delivery of emergent care to the preterm neonatal population. Neonates in the NICU are continuously monitored using advanced and sophisticated monitoring equipment, and there is ready and immediate access to equipment, medications, and skilled personnel that may be needed to address emergent developments. Interventions such as endotracheal intubation, MV, and traditional surfactant administration

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were readily available to all study subjects if clinically indicated in accordance with the high-level standard-of-care customary in the NICU.

Neonates were followed for the primary phase efficacy and safety evaluations through 36 weeks PMA, hospital discharge, hospital transfer, or death (whichever occurs first). For the longer-term follow-up phase, neonates were to be evaluated by phone at 6-months corrected age and at a visit at 12-months corrected age, at which time a physical examination was to be performed, including an abbreviated neurologic assessment. The longer-term follow-up was not completed as the study was terminated prior to any subjects completing this phase.

**Number of Subjects (estimated and actual):**

Number estimated: Approximately 130
Number enrolled/treated: 12/12
Number completing study: 12
Number discontinued: 0
Number discontinued due to adverse event (AE): 0

**Diagnosis and Main Criteria for Entry:**

The study population consisted of preterm neonates from 26 to 32 completed weeks PMA with RDS. Each subject must have met all of the following inclusion criteria to be enrolled in this study:

1. Signed ICF from legally authorized representative. Where allowed, it is recommended that consent is obtained antenatally.
2. Gestational age of $26^{0/7}$ to $32^{6/7}$ weeks PMA.
3. Successful implementation of non-invasive support or ventilation within 30 minutes of birth.
4. Spontaneous breathing.
5. Investigator determination of RDS. A chest x-ray should be obtained before treatment to confirm the diagnosis.
6. Within the first 6 hours after birth, requires an nCPAP of 5 to 7 cm $H_2O$ that is clinically indicated for at least 15 minutes with an $FiO_2$ of $\geq 0.25$ to $\leq 0.35$ to maintain $SpO_2$ of 90% to 95%. Transient (< 5 minutes) $FiO_2$ excursions outside this range do not reset the time requirement.

**Test Product, Dose and Mode of Administration, and Batch Numbers:**

Subjects randomized to the active treatment groups were administered an investigational drug-device combination product, lucinactant for inhalation, in conjunction with nCPAP. Reconstituted lyophilized lucinactant (reconstituted with sterile water for injection) was aerosolized by the investigational ADS device and introduced into the nCPAP circuit.

The theoretical inhaled dose (in mg TPL/kg) can be controlled based on the duration of exposure to the aerosol. This inhaled dose is a function of the concentration of lucinactant in the aerosol, the amount of aerosol inhaled by the subject (estimated by the subject's minute ventilation, assuming that all gas inhaled by the subject contains the same concentration of aerosol), and the duration of exposure to the aerosol. Because of losses that occur as the lucinactant aerosol travels from the ADS to the patient interface, approximately 35% of the reconstituted lucinactant aerosolized by the ADS was emitted and was available to be inhaled.

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Repeat doses were given ≥20 minutes from completion of the previous dose up to 36 hours after completion of randomization if subjects had a sustained (≥30 minutes) need for $FiO_2$ to maintain $SpO_2$ of 90% to 95%, unless it was unsafe to do so in the judgment of the investigator. Masking procedures for the initial dose were followed for repeat doses.

**Planned Test Product Treatments**

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| 160 mg/kg | 160 mg TPL/kg of lucinactant for inhalation, delivered as two consecutive 50-minute administrations, in conjunction with nCPAP (n ≈ 65)<br>Up to 3 repeat study treatments of lucinactant for inhalation 80 mg TPL/kg are to be given if repeat treatment criteria met. |

The lyophilized lucinactant lot/batch number G17003 was used.

**Reference Therapy, Dose and Mode of Administration, and Batch Numbers:**

Subjects in the nCPAP Only group received nCPAP alone. Batch numbers are not applicable.

Subjects randomized to the control (nCPAP only) group continued to receive nCPAP alone; in order to maintain masking, "sham" study drug treatment was used: the ADS was brought to the bedside but was not used, and no active study drug was administered.

Repeat dosing were given ≥20 minutes from completion of the previous dose up to 36 hours after completion of randomization, as was described for the active treatments. Masking procedures for nCPAP Only for the initial dose were followed for repeat doses.

**Planned Control Treatment**

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| nCPAP Only | Continuous nCPAP with sham drug treatment for 110 minutes (n ≈ 65)<br>Up to 3 repeats of 50-minute sham treatments are to be given if repeat treatment criteria are met |

**Study Duration:**

First enrollment to last enrollment: 18 April 2020 – 19 January 2021. The planned duration of the primary phase study was from randomization through 36 weeks PMA or 28 days of life (whichever was later), with a one-year corrected age follow-up phase. However, due to business considerations, enrollment for the study was paused on 30 November 2020, and the study was subsequently terminated on 10 December 2020. The study termination was not due to any safety concerns with lucinactant or the ADS. Subjects were followed through the primary phase endpoint, but the follow-up phase was cancelled. The study completion date was 19 January 2021.

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**Criteria for Evaluation:**

**Efficacy:**

The primary endpoint for this study was the number of subjects with respiratory failure due to RDS or death within the first 28 days of life. Respiratory failure due to RDS is defined as intubation (including intratracheal catheter placement) for MV and/or surfactant administration.

The key secondary endpoints of this study included the evaluation of the following:

1. Respiratory failure through 72 hours and 28 days of life
2. Time to respiratory failure through 72 hours and 28 days of life
3. BPD and survival without BPD at 36 weeks PMA
4. Severity of BPD at 36 weeks PMA
5. Oxygen saturation and use of supplemental oxygen
6. All-cause mortality through 28 days of life and 36 weeks PMA

Other secondary endpoints of this study included the evaluation of the following:

1. Common complications of prematurity through 36 weeks PMA (IVH, periventricular leukomalacia [PVL], pulmonary hemorrhage, apnea, NEC, patent ductus arteriosus [PDA], acquired sepsis, ROP).
2. Duration of MV and oxygen requirement through 36 weeks PMA
3. Changes in $FiO_2$, $PCO_2$, and $SpO_2$ over the first 72 hours of life, and over the first 7 days of life for $FiO_2$
4. Number/duration of and reason for re-hospitalization and urgent care visits through 12 months corrected age.
5. Respiratory medications through 12 months corrected age.

**Safety:**

The safety and tolerability endpoints were assessed during the primary phase through 36 weeks PMA, NICU discharge, hospital transfer, or death, whichever occurred first, as described below.

1. All-cause mortality through 28 days of life (date and time of death, if applicable)
2. AEs, including adverse device effects (ADEs) and AEs of special interest including AEs during the dosing period, complications related to placement of bi-nasal prongs, and air leak. AEs that are ongoing at 36 weeks PMA will be followed for an additional 30 days
3. Concomitant medications
4. Use of respiratory support and supplemental $O_2$, including the following:
    a. Need for endotracheal intubation and MV
    b. Mode of respiratory support, including oxygen only (without positive pressure)
5. Physical examinations
6. Assessments of the following:
    a. Vital signs
    b. $O_2$ saturation, as determined by pulse oximetry (SpO2)
    c. Chest radiography prior to intubation
7. Monitoring of $PCO_2$ and $FiO_2$

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**Technical Performance:**

The technical performance of the device was evaluated using the following parameters.

1. Information from touchscreen display:
    a. Total treatment duration
    b. Total amount dispensed
    c. Number of pauses
    d. Total time paused
2. Issues associated with device tubing (eg, CPAP tubing detachments, aerosol tube detachments, proximal pressure port obstruction, aerosol tube condensate obstruction).
    a. The number of the detachments that are intentional and unintentional will also be recorded
3. Aerosol or study drug (liquid) leakage before the subject interface (eg, disconnect of the inspiratory circuitry).
4. Occurrence of alarm signals before, during, or after treatment.
5. Any automatic system shutdowns with an associated error code.
6. Inability to maintain nCPAP, with a description.
7. ADS temperature alerts (high or low).

**Statistical Methods:**

The statistical analysis of both the primary and secondary objectives was based on all enrolled preterm neonates who received study therapy. The first 2 subjects at each site, which were treated with open-label active therapy were summarized separately.

For the efficacy analysis, all randomized subjects who received study therapy (modified intent-to-treat [mITT]) and subjects with no major protocol deviations (per-protocol) were to be evaluated, based upon the treatment group to which they were randomized. However, due to early termination of the study, only the ITT (all randomized/enrolled subjects) and safety populations (enrolled subjects that received study treatment) were utilized. Since all subjects who were randomized received treatment, the two populations are equivalent.

All continuous variables (eg, weight, body temperature) were summarized using number (n), mean, standard deviation (SD), median, 1st quartile, 3rd quartile, minimum, and maximum. All discrete variables (eg, sex, AEs, common complications of prematurity), were summarized using frequency (n) and percent. Sites were not pooled.

**Results:**

A total of 31 subjects were screened and 12 (39%) subjects were randomized into this study from 18 April 2020 to 03 November 2021 at 3 of 4 active study centers in Poland. Efficacy analyses were based on the intent-to-treat (ITT) population; safety analyses were based on the safety population. No subjects died during the study.

All subjects were Caucasian and non-Hispanic as is typical for enrollments in Poland. Most subjects were male at a gestational age of 31 weeks PMA. The vast majority of births were by C-section and only 1 subject was from a multiple birth.

Most subjects had 4 treatments (initial and 3 repeats); 2 subjects had each of 1, 2, and 3 treatments.

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Efficacy:

nCPAP failure was defined as intubation for mechanical ventilation or surfactant administration, or death due to RDS. For the primary endpoint, a total of six subjects in the ITT population experienced nCPAP failure. There was a slightly higher percentage of failures during the open-label phase compared to the double-blind phase; however, given the small numbers, it is not possible to draw conclusions between study phases or between treatment groups. No RDS-related death was observed.

Comparisons between treatment groups for complications of prematurity are not possible given the small number of subjects at the time the study was terminated, but results are consistent with previous studies with AEROSURF, with the exception that no subjects developed BPD during this study.

Due to the early termination of this study, efficacy conclusions cannot be drawn; however, results are consistent with previous studies with AEROSURF.

**Safety:**

Lucinactant for inhalation was generally well tolerated. There were no deaths in this study. A total of 3 SAEs were experienced by 2 subjects in the AEROSURF group (no SAEs were reported in the nCPAP only group). The SAEs included pneumothorax and pneumomediastinum experienced by one subject, and worsening congenital partial duodenal atresia experienced by one subject. All the SAEs were reported as unlikely and not-related to the study treatment.

A total of 2 subjects in the AEROSURF group and 1 subject in the nCPAP Only group experienced peri-dosing events. For these 3 subjects, all peri-dosing events occurred during repeat dosing with the exception of 1 incidence of apnea for a subject in the AEROSURF group.

All subjects experienced at least one AE. Overall, the most common events were anaemia, oxygen saturation decreased, apnoea, and neonatal jaundice. The events are typical for this patient population.

In general, the ADS functioned as intended. Study treatment pauses occurred for a variety of reasons(eg, temperature out of range, cartridge clog), but the vast majority of doses (77%) were administered without issue.

**Discussion and Overall Conclusions:**

From 18 April 2020 to 19 January 2021, 12 preterm neonates 26 to 32 completed weeks PMA participated in this study. All 12 subjects received study treatment and constitute both the Intent-to-Treat and Safety populations.

A total of 6 subjects experienced intubation for the purpose of surfactant administration or MV (nCPAP failure). Four (67%) of the failures occurred during the open label period and 2 (18%) during the double-blind period. The pattern of higher nCPAP failure rates in early subjects (ie, learning effect) was noted previously (Study 03-CL-1202). The single nCPAP only subject did not experience nCPAP failure. It is not possible to determine the effect of AEROSURF given the small number of subjects. No RDS-related death was observed.

Comparisons between treatment groups for complications of prematurity are not possible given the small number of subjects at the time the study was terminated, but results are consistent with previous studies with AEROSURF, No subjects developed BPD during this study which is consistent with previous AEROSURF studies, which have shown

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a reduction in the overall incidence and severity of BPD, regardless of whether the subject was ultimately intubated or not. Published literature have shown higher overall rates of BPD in this population.

Lucinactant for inhalation was generally well tolerated. There were no deaths in this study. A total of 3 SAEs were experienced by 2 subjects in the AEROSURF group (no SAEs were reported in the nCPAP only group). The SAEs included pneumothorax and pneumomediastinum experienced by one subject, and worsening congenital partial duodenal atresia experienced by one subject. All the SAEs were reported as unlikely and not-related to the study treatment.

All subjects experienced at least one AE. Overall, the most common events were anaemia, oxygen saturation decreased, apnoea, and neonatal jaundice. The events are typical for this patient population.

A total of 2 subjects in the AEROSURF group and 1 subject in the nCPAP Only group experienced peri-dosing events. Peri-dosing events generally occurred during repeat dosing.

In general, the ADS functioned as intended. Study treatment pauses occurred for a variety of reasons, but the vast majority of doses (77%) were administered without issue.

In summary, given the small number of subjects, it is not possible to draw definitive efficacy or safety conclusions. However, results are consistent with previous studies, although in this study, no subjects developed BPD. Lucinactant for inhalation was generally well-tolerated and no specific safety concerns were noted.

Results of this study indicate that further development of lucinactant for inhalation is warranted.

**Date of Report**: 27 October 2021