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Respiratory distress syndrome of the newborn and transient tachypnea of the newborn diagnosis

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1 *Works for me* dx.doi.org/10.17504/protocols.io.bavtie6n

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ABSTRACT

The authors detailed describe the standard procedures for immaturity-related respiratory disorders during the first 72h of life. These disorders are respiratory distress syndrome of newborn (SDR) and transient tachypnea of the newborn (TTN), secondary outcomes in the International Clinical Trials Registry Platform under the numbers **RBR-3f5bm5** and **RBR33rnjf**.

It shall be used by the multicenter team of researchers, duly trained in accordance with the Good Clinical Practice Protocol, during the prospective evaluation of enrolled newborns. Also, this protocol is complementary documentation for the scientific publications related to the clinical trials:

"Prematurity detection evaluating interaction between the skin of the newborn and light: protocol for the preemie-test multicentre clinical trial in Brazilian hospitals to validate a new medical device".

"Premature or small for gestational age? International multicenter trial protocol for classification of the low birth weight newborn through the optical properties of the skin".

GUIDELINES

The scientific references for the diagnosis of respiratory distress syndrome of newborn (RDS) and transient tachypnea of the newborn (TTN) were:

1 - Liszewski MC, Stanescu AL, Phillips GS, et al. Respiratory Distress in Neonates: Underlying Causes and Current Imaging Assessment. Radiol Clin North Am 2017;55:629–44. 7.

2 - Reuter S, Moser C, Baack M. Respiratory distress in the newborn. Pediatr Rev 2014;35:417–29. 20.

3 - Silverman, W. A., & Andersen, D. H. (1956). A controlled clinical trial of effects of water mist on obstructive respiratory signs, death rate and necropsy findings among premature infants. *Pediatrics*, *17*(1), 1-10.

MATERIALS TEXT

Standardized Clinical Trial Data Collection Form and Tablet for recording data of the study

SAFETY WARNINGS

The newborns received treatment for RDS, TTN and other complications, according to the best clinical practice and with the local protocols, without any influence of this study.

BEFORE STARTING

Identify the sources of the hospital records during the first 72 hours of life: medical records, laboratory and radiological assessments of the newborn.

Respiratory distress syndrome of the newborn

1 **The following clinical characteristics characterize this condition**

1.1 a) Tachypnea that persists after 2 hours of life without respiratory distress or mild respiratory distress (maximum score of 3 - according to a clinical description by Silverman Anderson Bulletin (1956).

b) Self-limited tachypnea, worsening up to 24 hours and later improvement, with resolution within 72 hours of life or discharge from hospital.

c) Newborns with diagnosed extrapulmonary conditions who have tachypnea (cardiac, neurological, metabolic) will be excluded from the study.

1.2 Other complementary findings that may or may not be present during data collection were:

a) Chest X-ray showing diffuse interstitial infiltrates with distribution pattern from the hilum, lobar fissure thickening, pleural effusion (usually small) or opacity for perihilar reinforcement (in severe cases). There may be mild to moderate cardiomegaly.

b) Respiratory distress was assessed according to the Silver Andersen respiratory severity score (RSS) for both respiratory disorders

Transient tachypnea of the newborn

2 **The following clinical characteristics characterize this condition**

2.1 A. Tachypnea that persists after 2 hours of life with signs of progressive worsening respiratory distress

B. Tachypnea onset within the first 6 hours of life, worsening within 24 hours and requiring ventilatory support.

C. Absence of extrapulmonary conditions that cause tachypnea from other causes such as cardiac, neurological, metabolic, and infectious. However, when there is no perinatal asphyxia (due to these diagnoses).

2.2 Criteria A + B + C were considered mandatory for the diagnosis. Other complementary findings that may or may not be present:

a) Use of surfactant in the first 24 hours of life.

b) Chest X-ray performed within 24 hours of life (or before surfactant) showing granular opacity or diffuse pulmonary reticulogranular infiltrate (ground-glass appearance) and reduced lung volume with air bronchogram (indicative of surfactant`s deficiency).

c) Saturation below target saturation (92-95%) with progressive worsening and need for higher levels of FiO2 (with FiO2 above 35 to 45 to maintain PO2 > 50mmHg - blood gas revealing respiratory acidosis)

Diagnosis confirmation by the experts

3 Two experts in neonatology reviewed medical records to confirm the diagnosis confirmation of SDR and TTN. All the criteria, including X-ray, laboratory assessments, clinical evolution, aimed to exclude other causes of ventilatory support as sepsis, meconium aspiration syndrome, birth with acidosis.

4

We expect to identify SDR and TTN with a set of criteria based on scientific references.

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