

Jan 27, 2020

Version 2

Respiratory distress syndrome of the newborn and transient tachypnea of the newborn diagnosis V.2

DOI

<https://dx.doi.org/10.17504/protocols.io.bbsninde>



Marconi Augusto Aguiar dos Reis¹, Roberta Maia C Romanelli¹, Zilma Reis¹

¹Universidade Federal de Minas Gerais



Zilma Reis

UFMG

Create & collaborate more with a free account

Edit and publish protocols, collaborate in communities, share insights through comments, and track progress with run records.

Create free account

OPEN  ACCESS



DOI: <https://dx.doi.org/10.17504/protocols.io.bbsninde>

Protocol Citation: Marconi Augusto Aguiar dos Reis, Roberta Maia C Romanelli, Zilma Reis 2020. Respiratory distress syndrome of the newborn and transient tachypnea of the newborn diagnosis . **protocols.io**

<https://dx.doi.org/10.17504/protocols.io.bbsninde>

Manuscript citation:

Premature or Small for Gestational Age Discrimination: International Multicenter Trial Protocol for Classification of the Low-Birth-Weight Newborn Through the Optical Properties of the Skin <https://www.researchprotocols.org/2020/7/e16477/>

License: This is an open access protocol distributed under the terms of the **Creative Commons Attribution License**, which permits unrestricted use, distribution, and reproduction in any medium, provided the original author and source are credited

Protocol status: Working

We use this protocol in our group and it is working New version on 01/26/2020 to adjust typos in steps subheadings

Created: January 25, 2020

Last Modified: January 27, 2020

Protocol Integer ID: 32302

Keywords: Respiratory distress syndrome of newborn, transient tachypnea of newborn, respiratory disorders of newborn, prematurity, transient tachypnea of the newborn diagnosis, newborn diagnosis, newborns to rd, respiratory distress syndrome, respiratory distress, transient tachypnea, related respiratory disorders diagnosis, enrolled newborn, respiratory disorders diagnosis during the first 72h, test multicentre clinical trial in brazilian hospital, protocol for the preemy, ttn diagnosis, low birth weight, international multicenter trial protocol for classification, new medical device, international clinical trials registry platform, good clinical practice protocol, clinical trial, prematurity detection

Abstract

The authors detailed describe the standard procedures for immaturity-related respiratory disorders diagnosis during the first 72h of life. These disorders are respiratory distress syndrome of newborn (RDS) 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 following the Good Clinical Practice Protocol, during the prospective evaluation of enrolled newborns to RDS and TTN diagnosis.

Also, this protocol is corresponding 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 premie-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."

New version on 01/26/2020 to adjust typos in steps subheadings



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

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 start

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 the respiratory distress syndrome of the newborn (RDS)**
 - 1.1 A respiratory condition characterized by the onset of tachypnea with respiratory distress and worsening in 24 hours and increased need for ventilatory support.
 - A. Characteristic clinical findings: onset of tachypnea in the first hours of life, worsening in 24 hours and increased need ventilatory support during this period.
 - B. Chest X-ray examination: performed in the first 24 hours of life (or before surfactant) revealing granular opacity or diffuse pulmonary reticulo-granular infiltrate (ground-glass appearance) and reduced lung volume, with air bronchogram (indicative of surfactant deficiency).
 - C. Other findings that may be present:
 - Improvement after surfactant.
 - Saturimetry below 92-95%, with progressive worsening and need of higher fraction of inspired oxygen (FiO_2) above 35 to 45% to maintain $\text{PO}_2 > 50\text{mmHg}$; blood gas compatible with progressive pulmonary insufficiency.
 - 1.2 NOTE: Diabetes mellitus in pregnancy and the absence of the use of antenatal corticosteroids for fetal maturation (ACFM) increase the possibility of RDS diagnosis.

Transient tachypnea of the newborn

- 2 **The following clinical characteristics characterize the transient tachypnea of the newborn (TTN)**
 - 2.1 A. Tachypnea that persists after 2 hours of life, with mild respiratory distress, according to the Silverman Anderson Bulletin, if possible.
 - B. Self-limited tachypnea worsening up to 24 to 48 hours and later improvement. Resolution frequently up to 72 hours, until the 5th day of life.
 - C. Newborns who have diagnosed extrapulmonary conditions that also have tachypnea: infection, cardiological, neurological, metabolic diseases will be excluded from the



diagnosis.

D. Chest radiography showing diffuse interstitial infiltrate with distribution pattern from the hilum, thickening of the lobar fissure, or opacity by perihilar reinforcement. There may be mild to moderate cardiomegaly.

- 2.2 OBS: neonatal respiratory distress associated with Intrauterine growth retraction (IUGR) and in cases that antenatal corticosteroids for fetal maturation (ACFM) was not used, has less chance of being RDS and greater possibility of TTRN.

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

Expected result

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