Code **HIM 2017-055**

Clinical Efficacy of Respiratory Pediatric Physiotherapy on a Child With Hospital Treated Pneumonia: Single-Blind Clinical Trial

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SUMMARY
Pneumonia poses a public health problem in México, it is the main cause of mortality and hospital intervention in children younger than 5 years old according to the 2012 national survey of health and nutrition by ENSANUT. The WHO estimates an annual growth trend of 8 million new cases in Latin America, of which 9% require hospitalization. Hospital Treated Pneumonia lengthens a hospital stay by 5 days on average, which implies a sizable expense from the public health budget.
The treatments recommended by guides and manuals in our country are based on the use of a series of antipyretics, analgesics and antibiotics, disregarding the problems caused by the detriment of the respiratory functions caused by pneumonia.

PROBLEM STATEMENT, the accumulation of secretions in the bronchopulmonary air network promotes the detriment of respiratory functions generating hypoxia and causing a decrease in the cardiac output requiring the use of mechanical ventilation and hemodynamic support. It is intended to control the accumulation of secretions by means of Respiratory Pediatric Physiotherapy (RPP) and to evaluate its effectiveness counting on biological plausibility.

The OBJECTIVE of this research protocol is to evaluate the effectiveness of RPP compared to postural drainage plus compression to the muscle belly of the upper limbs, as an adjuvant treatment for children with pneumonia. It is expected that the clinical severity decreases by 1.5 in the Wang score (a modification of the Silverman score), with a standard deviation of 2.6 points and a decrease of two days in the hospital stay with a α 0.05 in a one-tail test, a P of 80% and a 95.5% confidence interval.

METHODOLOGY, the protocol design corresponds to a single-blind trial. The population will consist of children aged from 0 to 8 years old diagnosed with pneumonia with a development time less than 7 days. The participants who comply with the selection criteria will be grouped in blocks of two using a randomization software (www.radomization.com).
The sample calculation corresponds to 40 participants per group. The intervention group will be exposed to techniques such as prolonged slow expiration, controlled expiratory flow exercises, tracheal pumping and tracheal reflex. The control group will be subject to postural drainage plus compressions to the muscle belly of the upper limbs. Both groups will go through 10 sessions: One daily session from Monday to Friday with a duration of 10 to 15 minutes each.
The Wang score (a modification of the Silverman score) will be used to measure the clinical severity and a pulse oximeter ChoiceMMed MD300C5 for SpO_2 and heart rate readings, the medical records will be consulted during the hospital stay.

DATA ANALYSIS PLAN, to prove whether there are or not statistical differences in and between both groups a Mann-Whitney U test will be used. The weightings from the Wang score (a modification of the Silverman score) will be considered before and immediately after the intervention maneuvers, and after 15, 30 and 120 minutes after said maneuvers have been performed.

BACKGROUND

The detriment of respiratory functions is one of the main sequels left by pneumonia, however, its treatment (curative, symptomatic or preventive) is not taken into consideration by the Mexican norm of "prevention and control of acute respiratory infections (ARI's) during first care" NOM-024-SSA2, nor by the 2011 guides for the treatment of nosocomial pneumonia updates from the department of infectiology at the Hospital Infantil de México Federico Gómez. In contrast, countries like Chile, [*1,2] Belgium, [*3] France,[*3,4,5] Spain[*4,6] and Switzerland[*7] have turned to RPP during the three levels of public health care as an strategy to combat said detriment.

In Chile, over a million physiotherapists are part of the national program "prevention and handling of acute respiratory infections in children". [*2]

In Switzerland, 4% of outpatients and 14.4% of hospitalized patients received said treatment during 2006. [*7]

In Spain, during 2007, 7.3%of nursing babies treated in top class hospitals received RPP. [*8]

There are reports of its use in countries such as Argentina, [*9] Brazil, [*10] Israel[*11] and the United Kingdom. [*12,13]

During 1998 to 2008, the mortality rate caused by ARIs decreased in Mexico by 46% and in Chile by 70%. [*14] There is probability of a co-relation between the inclusion of RPP in Chile's health care system in 1990 and the countries' significant decrease in the rate of mortality by ARIs.

In our country the use of RPP is discrepant due to the use of techniques designed for adults (postural drainage, vibrations and percussions) applied on children, even though in 1994 *the Fédération Française de Kinésithérapie Respiratoire recommended not using it for pediatrics,* *[16] said techniques do not take into consideration the anatomophysiological or mechanical characteristics of newborns, nursing babies and children, which jeopardizes the health of the patient. [*17]

The collected published works about the clinical efficiency of RPP are not unanimous in their conclusions.
The strongest evidence of RPP on children with pneumonia comes from a systematic Cochrane review (SCR), *[18] which takes into consideration 3 randomized controlled trials (RCT) [*19,20,21] with a total of 255 participants (*Table 1).* The authors consider that the diversity in age range, intervention maneuvers, execution time and methodological inefficiency in the selected articles makes it impossible to reach a conclusion about their efficiency.

RPP prevents, enables and rehabilitates the pulmonary functions from physiological or structural alterations in the respiratory system. In a child, the main alterations are those caused by the accumulation of secretions (pneumonia, atelectasis, chronic obstructive lung disease, restrictive lung disease, collapsed lung, progressive proteolytic destruction of the bronchial wall structure, lung hyperinflation and lung abscess, just to name a few). Its objective is to control the accumulation of secretions considering the dynamics of fluids and the anatomophysiological characteristics of the normal development of the child, which are described in the paragraphs *Fundamentals of Respiratory Pediatric Physiotherapy Applied as Adjuvant Treatment for Pneumonia* and *Intervention Maneuvers*.

Table 1. Characteristics of the RCTs considered by the SCR[*18]

Author	Comparison	n	Results	Weaknesses
Lukrafka JL, et al. [*19]	Intervention: TV, CC, PEEP, ELTGOL and H C . Control: PD. Time: 3 times a day.	72	No differences during the HS (6 vs8, p=0.11).	CT and MT were used. Blinding not reported. Morphological stratification error. Chronometric stratification error. Stratification error due to comorbidity.
Paludo C, et al. [*20]	Intervention: CC, TV, PD, CP, HC and Aspiration of secretions (if needed). Control: Standardized medical treatment.	98	No statistical significance in clinical resolution (4 vs 4, p=0.84) or in the HS (6 vs 6, p=0.76).	CT were used. Blinding not reported. Clinical stratification error. Chronometric stratification error. Stratification error due to comorbidity.
Zhao SK, et al. [*21]	Intervention: CPAP (instrumental technique). Control: Standardized medical treatment. Time: During hospital stay.	94	No statistical significance in clinical resolution. At 12 hours from intervention 94.1 ± 0.9.	Intervention maneuver is instrumental. Stratification error by status. Morphological stratification error. Blinding method not described.

TV= thoracicHSibrations, CC= chest compressions, PEEP= positive end-expiratory pressure, CP= chest percussion, CPAP= continuous positive airway pressure, PD= postural drainage CT= conventional techniques, MT= modern techniques and HC= huff coughing.

Pneumonia

151 million new cases of pneumonia in children younger than 5 years old are reported worldwide, being the cause of 19% of deaths inside that age range, according to the WHO's newsletter from May 2008.

In Latin America 8 million new cases are registered each year, from which 9% require hospitalization. [*22]

In 2008 in Mexico, 15,096 cases were registered and during 2009 a death rate of 19.6 out of every one hundred thousand was reported in children younger than five years old.

In Mexico, pneumonia is a public health problem, since it is the first cause of death and hospital admission in children younger than 5 years old, according to the National Health and Nutrition Survey from 2012.

Nosocomial infections represent a worldwide health problem. A survey made to 21 hospitals in Mexico showed that nosocomial infections represent 25% of infections in our country, and their morbidity and mortality rate shows a discrepancy from 1 to 36 cases for every 100 hospital discharges depending on the geography and level of care. [*23]

Pneumonia is the acute multifactorial infection (caused by virus, bacteria or fungus) [*24,25] of the lung parenchyma, characterized by the presence of cellular exudation, inflammation and infiltration in bronchiole, alveolus and occasionally bronchus. [*26,27]
It can affect 1.a lobe 2.lobe segments 3.alveoli, or the 4.interstitial spaces. [*28]

In-hospital pneumonia (IP) may be classified as early, when it develops between the second and seventh day of the hospital stay (HS). Late, when it presents itself at the eighth day of HS. And ventilator associated, when it emerges after 48 hours of exposure to the ventilator. [*26]

IP prognosis has a 20% chance mortality rate while ventilator associated pneumonia has a 29%. [*29]

IP extends HS by 5 days on average, [*14] a condition that compromises the wellbeing of minors and increases the cost of its treatment, which in the public health system is covered by the Public Health Fund.

The diagnosis in children younger than 5 years old presents a certain level of complexity, that is why the WHO's guidelines from 2016 recommend the following diagnostic criteria:
1. Symptoms: Coughing, respiratory difficulties, oral rejection, abdominal pain.
2. Signs: Feber, tachypnea, intercostal retractions, nasal flaring, grunting, decrease in vesicular murmur, dullness to percussion, rales, wheezing.

The complementary studies from offices and laboratories for diagnosis include X-rays of the thorax, biopsy, cytology of the bronchial lavage and Gram Stain. [* 30,31,32]

Infection starts when germs enter the lower respiratory tract, either by aspiration or extension of an adjacent space. [*32] This produces a release of mediators of inflammation, alongside a dilatation of the blood vessels and a capillary leak that infiltrates the submucosa of the plasmic fluid and proteins, thus creating the **obstruction mechanism**. The edema inflames the mucosa and the plasmic exudate increases the volume of secretions, which become hyperviscous, increasing the difficulty of their expulsion. [*26,27]

The accumulation of secretions in the bronchopulmonary network reduces physiological dead space, gas exchange, inspiration time and pulmonary compliance, generating an increase in air resistance and respiratory frequency. Said pulmonary restrictions often conclude in bronchial hyperreactivity. The accumulation of secretions can also cause atelectasis or pneumonic restrictions.

Anatomophysiological characteristics of the child's respiratory system

The child's respiratory system has a high potential for cellular renewal, cicatrization and repair. Its position, dimensions and relations morph with age. The alterations suffered during its development can affect the morphology and functionality of the ribcage, airways, pulmonary parenchyma and vascular bed.

In a child, the ribcage is less efficient compared to an adult's due to its more horizontal positioning and flexibility of the sternum and ribs.

The larynx is situated higher, the epiglottis is of a smaller diameter and verticalized, the laxity of the cartilages promotes its own collapse during inspiration, and pulmonary compliance makes them prone to the collapse of peripheral airways.

Intercostal, supra sternal, subcostal retractions and xiphoid retraction are present when pulmonary restrictions occur, increasing the action of the respiratory muscles and calorie output [*33,34] This situation worsens with the hypoventilation that follows thoracic pains or pleural effusion due to compression of the pulmonary parenchyma, resulting in arterial hypoxia and an increase in the alveolar-arterial oxygen gradient.

Hyperventilation is a response to the inflammation of the parenchyma or the chemoreceptors due to arterial hypoxemia, increasing PaO_2 and decreasing $PaCO_2$. Arterial hypoxemia caused by alterations of ventilation and perfusion is proportional to the extension of the pneumonia, normocapnia and hypocapnia are dependent to the raise of the alveolar-arterial oxygen gradient.

Treatment

*Health organizations in Mexico base their conventional intervention on a diversity of antibiotics, analgesics and antipyretics recommended by the official norm **024-SSA2-11994**.*

Conventional handling can not estimate the possible benefits that the treatment of the deterioration of respiratory functions has on the public health system and the public funds. RPP as adjuvant treatment has biologic plausibility.

Fundamentals of Respiratory Pediatric Physiotherapy applied as Adjuvant Treatment for Pneumonia

Its intervention seeks to achieve respiratory prosperity, and not the treatment of the infection, that is why its intervention is an adjuvant treatment.

If the deterioration of pulmonary functions due to accumulation of secretions is not controlled, ends in the need of mechanical ventilation and hemodynamic support. [*35]

The deterioration of respiratory functions can be prevented or controlled by controlling the accumulation of secretions.

Physiotherapy application methodology is dependent on the evaluation of clinical manifestations. [*36] The choosing of the intervention maneuver must consider the following variables: age, stage of the natural history of the disease, physical exploration, its classification of chronic obstructive pulmonary disease, changes in pressure and the dynamics of fluids.

RPP maneuvers are based on manual techniques (on patients without awareness of movement) or on assisted active contractions of the inspiration and respiration muscles (on patients with awareness of movement) to modify pleural pressure, pulmonary volume and the pressure inside alveoli. The variations in pleural and transpulmonary pressure, and pleural pressure gradient must be greater than the resistance of the airways, elastic pressure an inertia.

PROBLEM STATEMENT

The accumulation of secretions within the broncho-pulmonary airway network causes the deterioration of respiratory functions (atelectasis, pulmonary hyperinflation, restrictive lung disease, collapsed lung, progressive proteolytic destruction of the bronchial wall structure, lung abscess, recurrent bronchial obstruction and *respiratory distress syndrome*) worsened to hypoxia and causing a decrease in cardiac output, which may need the use of mechanical ventilation and hemodynamic support. [*35]

RPP stimulates the control of secretion accumulation modifying pleural and intraalveolar pressure and pulmonary volumes through passive, active-assisted or active contractions of the inspiratory and expiratory muscles, altering the line of air flow at will. RPP consists of two stages:

1. Secretion sweeping: Secretions generate resistance to the line of air flow, turning laminar flow into turbulent flow. The handling at will of inspiration and expiration time increases the intensity of the turbulence and cilia movement, causing the secretions to detach due to the transmission of energy described by Newton's third law in the zones where secretions and line of air flow make contact.
prolonged slow expiration, FET and controlled expiratory flow exercises will be used.

2. Secretion expulsion: The expelling of secretions through the airways is wanted by stimulating deglutition and active or assisted coughing. Tracheal pumping will be used.

The control of secretion accumulation in the broncho-pulmonary airway network tends to decrease air flow resistance and respiratory frequency (RF), and to regain alveolar space, normalizing inspiration time, bronchial permeability and pulmonary mechanics.

The effectiveness of said techniques has not been proved, since present evidence combines them with techniques designed for adult patients.

Research questions:

1. What is the effectiveness of RPP in comparison to postural drainage (PD) plus muscle belly compressions to the upper limbs for the reduction of clinical severity (in Wang score (a modification of the Silverman score)) for a child with pneumonia, 15, 30 and 150 minutes after it is performed?

2. What is the effectiveness of RPP compared to PD plus muscle belly compressions to the upper limbs for the decrease in days of hospital stay for children with pneumonia?

JUSTIFICATION

25% of nosocomial infections in our country are in-hospital pneumonia.

In-hospital pneumonia increases hospital stay by 5 days on average and increases hospitalization costs.

If respiratory pediatric physiotherapy is proven to be useful, days in hospital stay and hospitalization costs may decrease.

Not performing this research protocol will promote the empirical prescription of said techniques by the public health system.

OBJECTIVES

General objective

To evaluate the effectiveness of RPP compared to PD plus muscle belly compressions to the upper limbs for the treatment of a child with pneumonia.

Specific objectives

To evaluate the prolonged effects (15, 30 and 150 minutes after intervention) of RPP on clinical severity (Wang score (a modification of the Silverman score)) in comparison to PD plus muscle belly compressions to the upper limbs for the treatment of a child with in-hospital pneumonia.

To evaluate the effect of RPP compared to PD plus muscle belly compressions to the upper limbs on the number of days of HS of children with pneumonia.

HYPOTHESIS

1. Children with pneumonia who receive RPP Will have a decrease of 1.5 points, with a standard deviation of 2.6 In the Wang score (a modification of the Silverman score), 30 minutes after it being performed.
2. Children with pneumonia will have a decrease in HS of two days, compared to those treated with PD plus muscle belly compressions to the upper limbs.

METHODOLOGY AND RESEARCH DESIGN

DESIGN

Single-blind randomized clinical trial

Population

1. Study universe: Hospitalized children with pneumonia at the infectiology service.
2. Study population: Children from 0 to 8 years old with a diagnostic of pneumonia (under WHO's criteria) with a development time less than 7 days.
3. Sample: With the support of the epidemiology department, a daily list of all new cases of pneumonia will be provided. Patients then will be included once the diagnostic established by the pneumonia infectiology service is obtained.

Sample size calculation

The calculation for a sample size for an error of α 0.05 in a one-tail test and a power of 80% is based on the values described by Postiaux[*37] in the difference between the groups 30 minutes after the intervention, during 10 sessions. The difference in the Wang score (a modification of the Silverman score) measurements between the two groups was of 1.5 points with a standard deviation of 2.6 points.

Sampling method

$$\Delta = 1.5$$

$$S = 2.6$$

$$n = 2S^2(Z_{\alpha/2} + Z_{\beta})/\Delta^2$$

$$n=2(2.6)^2(1.64+0.84)/(1.5)^2=\mathbf{37}$$

The participants' sample size will be of 40 per group, to obtain statistical differences in the decrease of the Wang score (a modification of the Silverman score) entre between both groups with a α 0.05 in a one-tail test and a power of 80%, considering a decrease of 36% and a standard deviation of 13%.

Randomization

1. A sequence of aleatory numbers in blocks of 2 will be generated in each of the study groups using the software randomization.com, done by a person foreign to the research.
2. Using the randomized numbers generated by the software, it will be decided what group each participant belongs to (control or intervention) and what maneuver will be assigned to them.
3. These numbers and their maneuvers will be placed inside dark envelopes.
4. The whole randomization and assignment sequence will be performed by a person foreign to the research and without the knowledge of the researchers. Support will be provided from the coordination for nursing research, who will select the personnel for the process.

Blinding

After the assignment of the procedure, it will be blinded for the collaborator capacitated to measure the Wang score (a modification of the Silverman score), heart rate, SaO_2 and registering the days of hospital stay posterior to the pneumonia diagnosis. Data capture will be performed by the personnel previously selected by the coordination for nursing research, without the knowledge of the researchers.

Selection criteria

Inclusion criteria:

1. Patients from the HIMFG with diagnosis of pneumonia (considering the diagnostic criteria of the WHO and the Guidelines for Nosocomial Pneumonia from the infectiology department at the HIMFG) registered by the department of in-hospital epidemiology:
   1.1. Diagnostic criteria:
   a. Radiological, clinical and from laboratory:
      1. Radiology: Counting with at least one of the following findings:
      2. New, progressive or persistent infiltrate.
      3. Consolidation.
      4. Cavitating.
      5. Pneumatocele in children younger than 1 year old.

   b. Signs, symptoms and laboratory data:
   At least one of the following findings.
      1. Core temperature > 38.5°C o < 36°C (or rectal temperature >38 C° for at least 30 minutes after discarding the cause of external overheating, for example: overclothing)

2. Tachycardia (with no evident clinical cause) >2 standard deviation for the age and persistent (30 to 60 minutes) o bradycardia in children < 1 year old defined as a heart rate < 10 percent for the age (in absence of vagus nerve stimulation, β-blockers or congenital heart defect).
3. Tachypnea defined as a respiratory frequency >2 standard deviation for the age or requirement of mechanical ventilation due to an acute process not related to an underlaying neuromuscular disease or secondary to general anesthesia.
4. Recently started purulent sputum, or changes in the characteristics of the sputum, or an increase of respiratory secretions, or an increase in endotracheal aspiration needs.
5. The starting or worsening of coughing, or of respiratory difficulties.
6. Rales.
7. Worsening of the blood gases exchange: Oxygenation index >3 or a drop of it in relation to previous measurements and/or a Kirby index <300 or a drop of it in relation to previous measurements. Both determinations indicate a worsening of respiratory functions.

2. Patients aged 0 to 8 years old.
3. A minimum HS of 72 hours.
4. Having informed consent.
5. Not having had previous RPP treatment.

Deferral criteria:

1. Presenting a fever state for more than three days. Performing physiotherapy increases the body's peripheral temperature.
2. Presenting an oxygen saturation below 80%.
3. Requiring mechanical ventilation.
4. Hemodynamic instability.
5. Presenting systemic inflammatory response syndrome.
6. Inotropic support.
7. Anatomical variants in the thorax.
8. Unstable thorax.
9. Esophageal atresia.
10. Pleural effusion, pneumothorax.
11. Alterations that compromise respiratory centers and/or the phrenic nerve.
12. Neuromuscular diseases that compromise respiratory mechanics.

Elimination criteria:

The existence of one or more of the following:

1. Refusal to colaboration by the responsibleperson or patient.
2. Barotrauma.
3. Ascites (grave).
4. Focal lung pneumatosis
5. Pulmonary embolism (contraindication of the thoracic physiotherapy maneuvers).
6. Tumors in the upper respiratory system, intra or extrathoracic.
7. Glossitis.
8. Immediate or mediate postoperative state of head, abdomen or thorax.
9. Use of mechanical ventilation.
10. Paient with cystic fibrosis

Inervention group

The intervention group (IG) will be subject to RPP. Techniques of slow expiration will be used (PSE and TP) and slow inspiration (CEFE) for the sweeping of secretions, during its expulsion forced expiratory techniques will be used (tracheal reflex).

10 sessions will be performed, one a day from Monday to Friday, with a duration of 10 to 15

minutes.

Intervention maneuvers

RPP consists of two steps, 1.the sweeping or detachment of secretions and 2.the expulsion of the secretions.

a. Prolonged slow expiration (PSE)
It is a passive manual technique for expiratory support. A slow manual thoracoabdominal pressure is performed, which starts at the end of the spontaneous breathing up until the residual volume. Its purpose is to improve lung deflation, avoiding zones of bronchial narrowing, facilitating the depuration of the bronchopulmonary periphery.
Positioning of the patient: Supine position, on a semi-hard surface.
Therapist's: At one side of the patient.
Maneuver: The cephalic proximity hand is placed on the manubrium of the sternum, and the caudal proximity hand under the xiphoid process. Manual gradual joint pressure is applied on the descending thoracic and abdominal zone at the end of the respiratory spontaneous time until reaching residual volume. [*36]

b. Tracheal pumping (TP)
Manual pressure is applied to the trachea, followed by a linear peristalsis movement from down to up, spreading a wave of pressure (pumping), at the same time a slight pressure is applied to the expiration simultaneous to the pumping.
Positioning of the patient: Supine position, on a semi-hard surface.
Therapist's position: At one side of the patient.
Maneuver: The patient is made to reach neck hyper-extension. Pressure is applied to the trachea using the thumb of the hand with the most cephalic proximity to the patient, an ascending movement is performed starting from the Jugular notch of the sternum to the cricoid cartilage. Abdominal pressure is applied during expiration using the most caudal hand to the patient. [*36]

c. Controlled expiratory flow exercises (CEFE)
This technique favors insufflation and the clearing of the Deep lung and the air spaces surrounding the inspiratory-dependent volume exchange zone. Its mechanical action is to stretch the lung parenchyma by means of a surrounding pleural depression. During the maneuver the air inspired through the pleurae in the periphery of the affliction penetrates the peripheral air spaces to be used during expiration time, freeing the bronchial network spaces that had been taken by the accumulation of secretions. [*36, 38.]

d. Forced expiration technique (FET)
Also accepted as the term expiratory flow acceleration (EFA). It is obtained by the energetic contraction of the expiratory muscles (mainly the abdominal ones). During the maneuver, the intrathoracic pressure of the oral discharge increases simultaneously, which produces a lower mouth discharge that that of coughing, that allows the tearing off of the secretions from the bronchial wall due to the apparition mechanism of the SPP (same pressure point). This situation responds to the function of viscosity, elasticity, mucus thickness, the level of adhesion to the bronchial wall and the flexibility of the bronchial wall. [*36]

Control Group

The control group (CG) will be subject to PD plus muscle belly compressions of the upper limbs for 10 sessions, one session a day from Monday to Friday, with a duration de 10 to 15 minutes per patient. Both groups will receive the usual treatment for pneumonia prescribed by their treating doctor.

Variables and measuring instruments.

Measurements will be performed before, and 15, 30 and 150 minutes after the maneuvers.
Clinical severity will be measured using the Wang score (a modification of the Silverman score) *(Table 3)*, which consists of 4 items:

1. Respiratory rate.
2. Wheezing.
3. Retraction.
4. General condition.

Every item has an ordinal measurement level of 0 to 3 points (possible values: 0,1,2,3), excluding general condition (with a value of 0 or 3 only).
With a maximum summation of 12 points and a minimum of 0 points. The higher the score, the higher the clinical severity.

Complementary measurements:

1. Heart rate.
2. SaO_2.
3. Lung occupancy in the x-ray that was taken when the diagnosis was made.

The results from the pediatric Wang score (a modification of the Silverman score) will be compared in and between the groups at the following moments: 1.Before intervention (baseline state), 2.immediately after intervention, 3.15 minutes after intervention and 4.30 minutes after that.

The following tool (*anex 2*) has been designed to measure the variables. The

resources needed for research development are:

1. Medical history.
2. Vital signs monitors.
3. Stethoscope.
4. Pulse oximeter.
5. Disposable latex gloves.
6. Mechanical aspiration

RESEARCH VARIABLES

Independent variables

1. Pediatric respiratory physiotherapy.
2. Postural drainage plus muscle belly compressions to the upper limbs.

Dependent variables

1. Clinical severity.
2. Days of hospital stay from the beginning of the pneumonia.

Confounding variables

1. Baseline disease.
2. Age.
3. Nutritional state.

Descriptive variables

1. Sex.
2. Reasons for check-in.
3. Heart rate.
4. Oxygen saturation (SaO2).
5. Lung occupancy.
6. Wang score.

Variables	Type	Instrument	Range
Clinical severity.*	Ordinal.	Wang score.	0-12 pts.
Heart rate.*	Discrete quantitative.	Pulse oximeter. ChoiceMMed MD300C5.	30bpm to 325bpm.
SaO_2.*	Discrete quantitative.	Pulse oximeter . ChoiceMMed MD300C5.	0% to 100%.
Lung occupancy.**	Nominal.	Simple X-ray of the thorax.	Identification of the percentage occupied by secretions and infiltrates, detect complications (atelectasis, effusion ,etc…).
Days of hospital stay from the beginning of the pneumonia.**	Discrete quantitative.	Clinical file.	0-180 days.
Age.***	Discrete quantitative.	Clinical file.	1 to 6 years 364 days old.
Sex.***	Nominal	Clinical file.	Masculine/femenine.
Baseline disease. ***	Nominal.	Clinical file.	Yes/No Specify.
Reason for check-in.***	Nominal	Clinical file.	Specify.
Complications of pneumonia from the momento of inclusion.***	Nominal.	Clinical file.	None/ Effusion/ Necrosis or pulmonary abscess/ Other (specify)

Measurements must be performed before intervention, immediately after, and 15, 30 and 150 minutes after. **Measurements will be performed before initiating treatment sessions and after they conclude. * Measurements will be developed previously to the randomized group assignation.*

GENERAL DESCRIPTION OF THE STUDY

Assessment prior to the study

1. All patients diagnosed with pneumonia who comply with the selection criteria will be invited to participate in the study, in case of accepting, those older than 8 years old will verbally agree and will be given forms of informed consent to sign.
2. Data obtained will be documented in a previously established data collection format (Anex 2).
3. If there is no contraindication for the procedure, then the maneuver will be assigned.

Initiation and evaluation of the assigned maneuver

1. The researcher will perform the maneuver according to group assignation.
2. Subsequently a collaborator, previously blinded to the maneuver and standardized for the Wang score (a modification of the Silverman score), will evaluate the Wang score 15, 30 and 150 minutes after its application.
3. Another collaborator will do a follow-up on the patients in order to register their hospital stay time posterior to the diagnosis of pneumonia.
4. The assigned maneuver will be performed once a day on the patient.

End of study

The study will end once the patient checks out of the hospital.

Quality control

The assessment of the efficiency will be performed by 2 collaborators blinded to the maneuver. One collaborator will assess the Wang score (a modification of the Silverman score), heart rate and SaO_2 and the other collaborator will register the days of HS.

DATA ANALYSIS PLAN

Descriptive statistic: There will be an assessment of the central tendency values, relative dispersion and disposition to evaluate the descriptive variables at the start and at the end of the studyin both groups, as well as the dependent variables after the intervention.

Inferential statistic:

1. The comparison in score of the descriptive variables in and between the groups will be performed using a Mann-Whitney U test.
2. A 95% confidence Interval is estimated.

The Wang score rates will be assessed in the measurements made before and immediately after the intervention, and 13, 30 and 150 minutes after.
To describe the measurement differences and to reject or not the hypothesis, a Mann-Whitney U test will be used.

LIMITATIONS OF THE STUDY

Due to the maneuver condition, the subject cannot be blinded, and only the researchers will be single-blinded, which confers a type of bias to the study.

TIMELINE

The timeline of activities is presented as a FORMAT ATTACHED to this document.

ETHICAL CONSIDERATIONS

The *2016 guide for the evaluation of ethical considerations of our institution* is presented as a FORMAT ATTACHED to this document.

Beneficence/Nonmaleficence

This is a MAXIMUM TO MINIMAL RISK study for participants, and it could cause reflux, vomit or irritability of the patient's emotional state (with all that implies). Potential benefit to the patient by improving their clinical severity and reducing the days of hospital stay. Potential Benefit to society by reducing the days of hospital stay, which in turn will reduce the cost of treatment for children with pneumonia.

Autonomy and respect

It will be clearly expressed to the patient or person responsible for them, every procedure they will become subject to, until their understanding is secured.

A Form of Informed Consent will be required *(Anex 3).*

We consider that due to the participants' ages it is not possible to require a Form of Informed Assent.

The anonymity of participants will be maintained, and the confidentiality of data will be maintained using a restricted database to which only the researchers have access to.

Justice: The participant population is in a vulnerable situation since they are minors. Nevertheless, the adult population is well enough informed and the results of this study seek to improve the care of this sector of the population.

The norms and standards for bioethics from the declaration of Helsinki have been considered, as well as the legal and juridical regimes for research current on Mexico (General Law of Health in Regard of Research in Human Beings).

BIOSECURITYCONSIDERATIONS

This research project does not have biosecurity implications, since no pathogenic agents or potential pathogens are handled.

The form from the biosecurity committee of our nation is presented as a FORMAT ATTACHED to this document.

PRODUCTS TO BE OBTAINED FROM THE STUDY

Assuming that the biostatistical results gathered do not reject the hypothesis, it is intended to divulge the results by elaborating a scientific poster and presenting it in various congresses and update conferences.

The following events are contemplated to divulge the results:

1. IIV Conferencia de actualización en pediatría. ALEPE. 2017.
2. 76° Congreso de las Américas de Neumología y Cirugía de Tórax. Sociedad Mexicana de Neumología y Cirugía de Tórax. 2017.
3. XVI International Congress on Pediatric Pulmonology. CIPP. 2017.
4. 49° Congreso Nacional SEPAR. 2017.
5. LXIV Congreso de la Asociación de Médicos del Hospital Infantil. 2017.
6. VII Congreso de SEFIP. 2017.

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