UNIVERSIDADE FEDERAL
DO RIO DE JANEIRO
CENTRO DE CIÊNCIAS DA SAÚDE
MATERNIDADE ESCOLA UFRJ

AMANDA DE PAULA SILVA

ANÁLISE DOS DESFECHOS CLÍNICOS DA ADMINISTRAÇÃO OROFARÍNGEA DE COLOSTRO EM RECÉM-NASCIDOS PREMATUROS DE MUITO BAIXO PESO

Rio de Janeiro

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Análise dos desfechos clínicos da administração orofaríngea de colostro em recém-nascidos prematuros de muito baixo peso

Trabalho de Conclusão de Curso do Programa de Residência Multiprofissional em Saúde Perinatal da Maternidade Escola da Universidade Federal do Rio de Janeiro, como requisito obrigatório para obtenção do título de Nutricionista Especialista em Saúde Perinatal.

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Rio de Janeiro

DESFECHOS CLÍNICOS DE RECÉM-NASCIDOS PREMATUROS SUBMETIDOS À COLOSTROTERAPIA EM UMA UNIDADE DE TERAPIA INTENSIVA NEONATAL DO RIO DE JANEIRO

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RESUMO

Análise dos desfechos clínicos da administração orofaríngea de colostro em recém-nascidos prematuros de muito baixo peso

Introdução: O colostro é a primeira secreção produzida pelas glândulas mamárias, presente até o 7º dia de vida. Apresenta importantes componentes imunomoduladores e fatores de proteção que

colostro (AOC) surge como uma opção em potencial para recém-nascidos de muito baixo peso (RNMBP; <1500g). **Objetivo:** analisar os desfechos clínicos de recém-nascidos prematuros (RNPT) submetidos à AOC. **Métodos:** Estudo longitudinal retrospectivo. Método de amostragem não probabilístico. Critérios de inclusão: RNPT submetidos ao protocolo da AOC. Critérios de exclusão: RNPT cujos dados da AOC não estavam disponíveis ou não receberam nenhuma dose e óbito nos primeiros dias de vida. Utilizou-se o teste Mann-Whitney para comparação das variáveis quantitativas e Wilcoxon para avaliação da evolução dos valores antropométricos, com nível de significância de 5% ($p<0.05$). **Resultados:** início da Terapia Nutricional Eenteral (TNE) (1 [1-1]); alcance do aporte pleno (11.0 [9.0-16.0]); recuperação do peso ao nascer (11 [7.0-14.0]). Início da AOC com 3 dias de vida e o número de doses totais 32.5 [21.0-44.0]. Diferença significativa na

do peso ao nascer em menos dias com maior número de doses ($p=0.07$). O tempo para aporte pleno foi significativamente maior e o tempo para recuperação do peso ao nascer foi significativamente menor quando considerado o início ≤ 3 dias ($p=0.023$). **Conclusões:** A AOC esteve associada ao tempo para recuperação do peso ao nascer e tempo para aporte pleno.

PALAVRAS CHAVES: administração orofaríngea de colostro, terapia imunológica oral,

Analysis of Clinical Outcomes of Oropharyngeal Colostrum Administration in Very Low-Birth-Weight Preterm Newborns

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Conflict of Interest

The authors have no conflicts of interest to declare.

Contribution to Authorship

AS, RM and PCP designed and planned the study, analysed the results and drafted reviewed all versions of the manuscript. BFN and LVC collected the data, analyzed the results and drafted the

Highlights

- Colostrum administration is associated with time to recover birth weight and time to full enteral feeding.
- Colostrum is important to Very Low-Birth-Weight Preterm's nutritional support.
- Full enteral feeding is more difficult when considering less doses of colostrum.

Abstract

Introduction: Colostrum is the first secretion produced by the mammary glands, present until the 7th day of life. It has important immunomodulatory components and protective factors that will contribute to the protection and development of the newborn. The oropharyngeal administration of colostrum (OAC) appears as a potential option for very low-birth-weight newborns (VLBW; <1500g). **Objective:** to analyze the clinical outcomes of VLBWs submitted to OAC. **Methods:** Retrospective longitudinal study. Non-probability sampling method. Inclusion criteria: VLBWs submitted to the OAC protocol. Exclusion criteria: VLBW s whose OAC data were not available or received no dose and death in the first days of life. The Mann-Whitney test was used to compare quantitative variables and Wilcoxon to assess the evolution of anthropometric values, with a significance level of 5% ($p < 0.05$). **Results:** start of Enteral Nutritional Therapy (ENT) (1 [1-1]); reach of full enteral feeding (11.0 [9.0-16.0]); recovery of birth weight (11 [7.0-14.0]). OAC onset at 3 days of life and the number of total doses 32.5 [21.0-44.0]. Significant difference in the weight in fewer days with a higher number of doses ($p = 0.07$). The time to full enteral feeding was significantly longer and the time for recovery of birth weight was significantly less when considering the onset ≤ 3 days ($p = 0.023$). **Conclusions:** OAC was associated with time to recover birth weight and time to full enteral feeding.

Keywords: oropharyngeal administration of colostrums; oral immunotherapy; colostrums; human milk; preterm newborn.

Abbreviations: ME – UFRJ: Maternidade Escola Universidade Federal do Rio de Janeiro (Maternity Hospital of the Federal University of Rio de Janeiro);**INJC:** Instituto de Nutrição Josué de Castro (Nutrition Institution Josué de Castro)**; WHO:** World Health Organization; **HM:** Human milk;**OAC:** Oropharyngeal Administration of Colostrum; **VLBW**: very low-birth-weight newborns; **NICU:** Neonatal Intensive Care Unit; **GA:** Gestational age; **EHM:** expressed human milk; **AGA:** appropriate for gestational age; **SGA:** small for gestational age; **ENT:**

Introduction

According to the World Health Organization (WHO), more than 1 in 10 births in the world were premature in 2010, about 15 million [1]. Brazil is among the 10 countries with the highest number of premature births in the world and in 2017 10.5% of births were premature births[2,3]. Prematurity is birth with gestational age (GA) less than 37 weeks, increasing the risk of morbidity and mortality the lower the GA and the birth weight[4]. Scenario where breast milk is highlighted as the main factor for maturation of systems and weight recovery[2,5].

Human milk (HM) is recognized by WHO as the most complete food for children and is also valued for benefits in addition to nutritional[6]. Colostrum is the first secretion produced by the mammary glands, present until the 7th day of life. Transitional food between the intrauterine period and extrauterine life[7,8], has important immunomodulatory components and protective factors that will contribute to development. [5,7–11]

In view of the importance of exposure to maternal colostrum in a timely manner, oropharyngeal administration of colostrum (OAC) appears as a potential option for very low-birth-weight newborns (VLBW; <1500g). This presupposes the absorption by the oral mucosa of small amounts of applied liquid and provides immune therapy[11,12]. Typically, an amount of 0.2 mL is divided between the two cheek mucous and massaged for absorption. In addition, raw expressed human milk, mainly expressed at the bedside, is indicated and should be used whenever possible, as pasteurization and refrigeration processes decrease the immunological potential[11–13].

Therefore, the objective is to analyze the clinical outcomes of VLBWs submitted to OAC in the institution. The present study hypothesizes that the early OAC, that is, with fewer days of life and a greater number of doses, is associated with better clinical outcomes.

Material and Methods

Retrospective longitudinal study with data on VLBW admitted to the NICU from January to December 2018 who underwent OAC at the institution. The non-probability sampling method was chosen, including all eligible patients. Inclusion criteria adopted: VLBWs submitted to the

and death in the first 7 days of life. Data collection was performed using medical records and the

The following independent variables were considered: Anthropometric (birth weight, length at birth, head circumference at birth), sociodemographic (age and maternal complications, GA at birth and sex), clinical (apgar score of the 1st and 5th minute and postnatal complications) and OAC (lifetime on initiation and number of doses). And, as dependent variables: Time to start ENT and to reach full enteral feeding, length of stay, recovery of birth weight and time of ventilatory support.

The classification of weight according to GA at birth was performed considering the Intergrowth-21st[15,16]international standard curve of postnatal growth, proposed by WHO. Anthropometry data at discharge were evaluated considering the Intergrowth-21st[15,16]international standard curve of postnatal growth of preterm infants up to 64 postconceptional weeks; performance of the respiratory tract through the total number of days that required ventilatory support; evolution of ENT (time to start, type of diet started and time to reach full enteral feeding); total time in days of hospitalization; time in days to recover birth weight and breastfeed at hospital discharge (type – exclusive, mixed or artificial).

The institution's OAC protocol [14] (elaborated in 2018) has all VLBW (<1500g) as an indication, and serious swallowing disorders with significant saliva accumulation and restrictions on breast milk are the contraindications[17]. The duration consists of the first seven days of life, often according to the diet prescription schedule (in case of "zero diet", maintained from 3/3h). Application of 0.1 mL of colostrum to the right and left oral mucosa (total of 0.2 mL), without removing the syringe from the mouth during the exchange, towards the oropharynx; massaging each side of the cheek for at least 10 seconds (performed before the diet). Colostrum of the maternal milking is used, which is expressed at the bedside or in the institution's human milk bank. Thus, the evaluation considered the life time when starting the OAC and the total number of doses performed[14].

The normality of the distributions was tested using the Shapiro-Wilk test. Descriptive statistical analysis represented by the median and interquartile range (P25; P75) due to the presence of sample asymmetry. Categorical data were summarized with absolute and relative frequencies.

used to assess the evolution of anthropometric values with a significance level of 5% ($p < 0.05$).

Results and Discussion

During the period studied, 56 VLBW were born, 50 were considered eligible for the study and had OAC prescribed according to the protocol. Of these, eight were excluded, five due to death and three because they had not received any dose of colostrum, resulting in a casuistry of 42 VLBW (Figure 1).

Table 1 shows that in all cases analyzed, there is at least one maternal complication, with the majority of cases being hypertensive syndromes (53.7%) followed by infectious complications (29.3%). More than a third (35.7%) of the casuistry were twin and the high rate of cesarean delivery (76.2%) stands out. Most (54.8%) of very preterm infants stand out and a high rate of adequacy of anthropometric measurements at birth.

As it is a therapy for VLBW, 21.3% of extremely premature infants, 54.8% very premature and 23.8% moderate preterm infants were found. The distribution of premature births in the gestational age subgroups is remarkably similar worldwide, which suggests a biological basis[1].

In relation to the evolution of nutritional therapy (table 1), the onset occurs in general on the first day of life of newborns (1 [1-1]), the type of diet initiated mostly is expressed human milk

the 11th day (11.0 [9.0-16.0]). As for the recovery of birth weight, this also occurred around the 11th day [7.0-14.0] and the median length of hospitalization was 37 days [19.75-67.00]. With

32.5 [21.0-44.0]. The type of breastfeeding at discharge in most cases was mixed (56.1%) followed by exclusive (26.9%) and artificial (17.1%) breastfeeding.

Early ENT is shown to be positive for preterms and, therefore, especially for VLBW, it should be started as soon as possible (within 6 to 12 hours after birth), if clinically stable, being considered feasible to start on the first day of life[18,19]. The data found in the present study go against the recent recommendations when we observe that the diet was started on the first day of life.

To start nutrition in newborns, the mother's own colostrum, preferably fresh, is recommended as the first option, the second option being pasteurized (donated) human milk and as the third choice the infant formula of premature infants. In 2012, it was evidenced in this

present study in 90.5% it started ENT with EHM and formula. This difference suggests that the association of OAC for VLBWs may have influenced an increase in early contact with HM. The receipt of majority HM as ENT in the 6thweek of life and at hospital discharge for the group submitted to OAC compared with the placebo group was previously demonstrated by another study[21].

The reach of full enteral feeding in ENT (11[9-16]) proved to be compatible with the recommendation that full enteral feeding be reached in 7 to 15 days after birth[19].

There was a median onset at 3 days of life of the OAC. Even though priority is given to starting therapy on the first day of life[14], there are difficulties within the clinical practice of this early start. OAC has limitations, namely: 10 to 20% of mothers were unable to supply colostrum for administration; colostrum was generally not available for administration before 2 days of life and 75 to 80% of scheduled administrations were performed[12].

Growth is seen as an indicator of well-being, especially in preterm infants. For that, intensive care with nutrition is necessary, especially in those born with GA less than 32 weeks[5,18,22]. The recovery of birth weight occurred around the 11thday of life, compatible with reports where it is considered that initial weight loss occurs, followed by the recovery of birth weight at 10 to 20 days of life[5,5,18,23].

When comparing clinical outcomes according to the total number of doses of colostrum (table 2), no significant difference was found. A tendency to recover birth weight in fewer days with a higher number of doses ($p=0.07$) stands out. When the outcomes were compared in relation to the beginning of OAC (table 2), a significant difference was found in relation to full enteral feeding and recovery of birth weight when the start was early (≤ 3 days). The time for full enteral feeding was significantly longer and the time for recovery of birth weight was significantly shorter when considering the start ≤ 3 days ($p=0.023$).

OAC has a positive effect in the literature: shorter time to reach full enteral feeding in the

at hospital discharge or potential influence with increased amount of EHM offered[24–29]. Other studies have not found a significant difference for the recovery of birth weight, time interval until

Regarding the reach of the full enteral feeding, the data of the present study are divergent, a randomized study in receiving OAC or placebo observed that the group that received colostrum reached 10 days before[24] and another observed a trend of shorter time[29]. No studies were found that have compared the time of start of OAC.

Otherwise, OAC provides an invaluable gain to the mother-baby binomial perceived in clinical practice. Breastfeeding and bonding are encouraged from the first moments of life, as maternal adherence to preterm care is still stimulated in the NICU, actively participating in the treatment of her own child[27].

Conclusion

In this study, it was possible to show that OAC was associated with the following clinical outcomes: time to recover weight at birth and time to full enteral feeding. Although there are still few positive effects of OAC findings on clinical outcomes, this represents a major challenge for the multiprofessional health team in the attention and care of VLBWs. Further studies are needed on the impact of OAC on clinical outcomes in order to elucidate the effects that are still considered inconclusive and to implement its expanded implantation in neonatal units.

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Conflict of Interest

"The authors have no conflicts of interest to declare".

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FIGURES

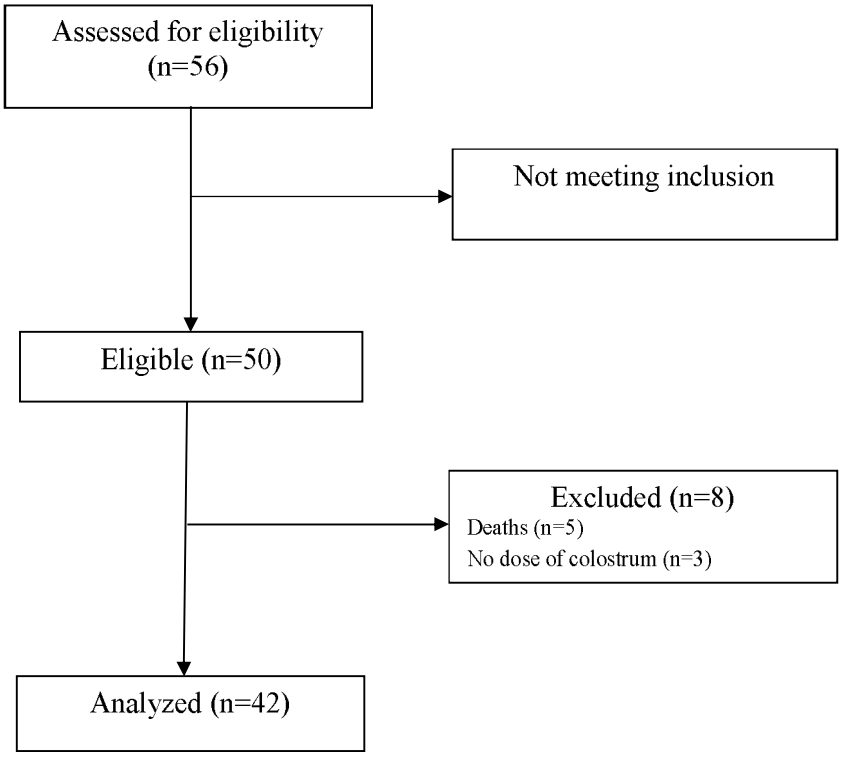

Figure 1: Data collection flowchart, Rio de Janeiro, 2020.

TABLES

Table 1: Sociodemographic, gestational, birth and clinical characteristics of VLBW, Rio de Janeiro, 2020

Variables	Median [Q25-75]/%
Mother's age (years; n=42)	28.0 [23.0-34.0]
Maternal complications (%; n=42)	
Hypertensive Syndromes (n=22)	53.7%
Infectious (n=12)	29.3%
Diabetes Mellitus (n=7)	17.1%
Type of pregnancy (%; n=42)	
Single fetus (n=27)	64.3%
Twin (n=15)	35.7%
Type of delivery (n=42)	
Vaginal (n=10)	23.8%
C-section (n=32)	76.2%
Sex (%; n=42)	
Male (n=26)	57.8%
Female (n=16)	35.6%
Gestational age at birth (weeks; n=42)	30.0 [28-25]
Classification of Prematurity (%; n=42)	
Extreme (GA ≤28 weeks; n=9)	21.4%
Very Premature (28 <GA <32; n=23)	54.8%
Moderate and Late (GA≥32 weeks; n=10)	23.8%
Apgar 1stminute (n=42)	7.0 [4.8-8.0]
Apgar 5thminute (n=42)	8.0 [7.0-9.0]
Birth weight (%; n=42)	
SGA (n=3)	7.1%
AGA (n=39)	92.9%
Length at birth (%; n=42)	
Appropriate for GA (n=34)	81.0%
Small for GA (n=5)	11.1%
Very small for GA (n=3)	6.7%
Head circumference at birth (%; n=42)	
Appropriate for GA (n=3)	92.9%
Microcephaly (n=1)	2.4%
Severe Microcephaly (n=2)	4.8%
Ventilatory Support (days; n=40)	1.0 [0.0-4.8]

Type of feeding initiated (n=42)	
EHM (n=2)	4.8%
Formula (n=2)	4.8%
Mixed (EHM + Formula; n=38)	90.5%
Recovery of birth weight (days; n=39)	11.0 [7.0-14.0]
Length of hospitalization (days; n=42)	37 [19.75-67.00]
Gestational age at NICU discharge (weeks; n=38)	35.5 [34.0-39.2]
Type of breastfeeding at NICU discharge (%; n=38)	
Exclusive Breastfeeding (n=11)	26.9%
Artificial Breastfeeding (n=7)	17.1%
Mixed Breastfeeding (n=23)	56.1%

Legend: AGA - appropriate for gestational age; SGA - small for gestational age; EHM - expressed human milk; OAC - oropharyngeal administration of colostrum; NICU - Neonatal Intensive Care Unit.

Table 2: Comparison of clinical outcomes of VLBW according to the total number of doses of oropharyngeal administration of colostrum and start in days of oropharyngeal administration of colostrum, Rio de Janeiro, 2020

Variables	Number of doses <32.5	Number of doses ≥32.5	p-value	Start ≤ 3 days	Start > 3 days	p-value
Start of enteral diet (days)	1.0 [1.0-1.0]	1.0 [0.5-1.0]	0.178	1.0 [1.0-1.0]	1.0 [1.0-1.0]	0.772
Ventilatory Support (days)	1.0 [0-3.5]	0.5 [0-5.8]	0.913	1.0 [0-5.5]	1.0 [1.0-2.0]	0.480
Reach of full enteral feeding (days)	14.0 [9.0-20.0]	10.5 [8.3-14.5]	0.158	13.0 [9.0-16.0]	8.0 [6.0-10.0]	0.013
Recovery of birth weight (days)	13.0 [10.0-14.8]	10.0 [6.0-13.0]	0.070	10.5 [7.0-13.0]	14.0 [13.0-16.5]	0.023
Length of NICU stay	40.0 [23.5-59.0]	34.0 [17.0-68.0]	0.900	40.0 [21.5-68.0]	31.0 [12.0-64.5]	0.421

Anexo 1.

UFRJ - MATERNIDADE ESCOLA DA UNIVERSIDADE FEDERAL DO RIO DE JANEIRO

Plataforma Brasil

PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: DESFECHOS CLÍNICOS DE RECÉM-NASCIDOS PREMATUROS SUBMETIDOS À COLOSTROTERAPIA EM UMA UNIDADE DE TERAPIA INTENSIVA NEONATAL DO RIO DE JANEIRO

Pesquisador: AMANDA DE PAULA SILVA

Área Temática:

Versão: 1

CAAE: 06383119.4.0000.5275

Instituição Proponente: Maternidade Escola da Universidade Federal do Rio de Janeiro

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 3.138.145

Apresentação do Projeto:

Trata-se de um estudo longitudinal retrospectivo com dados de recém-nascidos internados na unidade neonatal no período de Janeiro de 2018 a Dezembro de 2018 que realizaram a colostroterapia O presente estudo será realizado na Maternidade Escola da UFRJ (ME/UFRJ), localizada no Bairro das Laranjeiras. O método de amostragem escolhido será o não probabilístico sendo incluído todos os pacientes elegíveis durante o período do estudo. A coleta de dados será realizada por meio de consulta aos prontuários dos recém-nascidos e os protocolos utilizados pela equipe da Unidade Neonatal (UTIN, BLH e Nutrição). A coleta será realizada através de um formulário digital próprio (ANEXO I), elaborada pela pesquisadora. Como a coleta de dados será exclusivamente obtida pelos dados do prontuário e fichas arquivadas pela equipe será elaborado o Termo de
Compromisso de Utilização de Dados (TCUD) que garante a confidencialidade sobre os dados coletados bem como a privacidade dos conteúdos.

Objetivo da Pesquisa:

Objetivo Geral: Analisar os desfechos clínicos de recém-nascidos prematuros submetidos à colostroterapia na Maternidade Escola da Universidade Federal do Rio de Janeiro/ ME-UFRJ.

Objetivos Específicos: Descrever as características antropométricas e clínicas dos recém-nascidos

da amostra; Descrever os desfechos clínicos em recém-nascidos prematuros submetidos à colostroterapia na Maternidade Escola da UFRJ; Verificar a associação entre as características da colostroterapia (tempo de vida ao iniciar e número de doses) com os desfechos clínicos: tempo em suporte ventilatório, ocorrência de enterocolite necrotizante, sepse e evolução da terapia nutricional enteral (tempo para início, tipo de dieta iniciada e tempo para atingir a nutrição plena), tempo de internação, recuperação do peso ao nascer e aleitamento materno na alta hospitalar (tipo – exclusivo, parcial ou artificial).

Avaliação dos Riscos e Benefícios:

O estudo não acrescentará riscos adicionais à saúde e evolução dos neonatos, tendo em vista que os dados serão coletados por meio de consulta aos prontuários e protocolos utilizados pela equipe da Unidade Neonatal (UTIN, BLH e Nutrição). A pesquisadora se responsabilizará pela confidencialidade das informações pessoais dos participantes da pesquisa.

Como benefícios para os usuários, a presente pesquisa poderá subsidiar a prática clínica direcionada ao neonato na tentativa de otimizar o prognóstico e evolução destes, enquanto para a instituição, contribuirá com esforços para aperfeiçoar e valorizar uma terapia recém iniciada.

Comentários e Considerações sobre a Pesquisa:

Pesquisa relevante, tendo em vista a população de recém-nascido prematuros que poderá ser beneficiada.

Considerações sobre os Termos de apresentação obrigatória:

Todos presentes

Recomendações:

Muito embora conste que a pesquisa não acrescentará riscos adicionais, o caput do artigo V da resolução 466/2012 dispõe: "V – DOS RISCOS E BENEFÍCIOS

Toda pesquisa com seres humanos envolve risco em tipos e gradações variados."

Conclusões ou Pendências e Lista de Inadequações:

Não há.

Considerações Finais a critério do CEP:

UFRJ - MATERNIDADE
ESCOLA DA UNIVERSIDADE
FEDERAL DO RIO DE JANEIRO

Plataforma Brasil

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_1288379.pdf	24/01/2019 23:28:35		Aceito
Folha de Rosto	folhaderostoo.pdf	24/01/2019 23:26:42	AMANDA DE PAULA SILVA	Aceito
Projeto Detalhado / Brochura Investigador	ProjetoTCRAmanda2019Final.doc	24/01/2019 23:24:52	AMANDA DE PAULA SILVA	Aceito
Orçamento	orcamento.doc	23/01/2019 23:34:10	AMANDA DE PAULA SILVA	Aceito
Cronograma	cronograma.doc	23/01/2019 23:31:51	AMANDA DE PAULA SILVA	Aceito

Situação do Parecer:
Aprovado

Necessita Apreciação da CONEP:
Não

RIO DE JANEIRO, 08 de Fevereiro de 2019

Assinado por:
Ivo Basílio da Costa Júnior
(Coordenador(a))

A manuscript number has been assigned: NUT-D-20-01008

Dear Patricia,

Your submission entitled "Analysis of Clinical Outcomes of Oropharyngeal Colostrum Administration in Very Low Birth Weight Preterm Newborns" has been assigned the following manuscript number: NUT-D-20-01008.

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Kind regards,