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Victória Boëchat Feyo
Vias diagnósticas e terapêuticas de lesão labial em oncohematologia: relato de um caso pediátrico desafiador

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	ão labial em oncohematologia: relato de trico desafiador		
	Trabalho de conclusão de curso apresentado à Faculdade de Odontologia da Universidade Federal de Juiz de Foraçomo requisito parcial à obtenção do título de Cirurgiã-Dentista.		
Orientador: Prof ^a Dr ^a Gisele Maria Campos	s Fabri		

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VICTÓRIA BOECHAT FEYO

Vias diagnósticas e terapêuticas de lesão labial em oncohematologia: relato de um caso pediátrico desafiador

Trabalho de conclusão de curso apresentado à Faculdade de Odontologia da Universidade Federal de Juiz de Fora como requisito parcial à obtenção do título de Cirurgião-Dentista.

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RESUMO

Introdução: pacientes onco-hematológicos apresentam aumento do nível de trombose e sangramentos decorrentes do tratamento e da doença. Materiais e Métodos: descreve-se um caso de lesão hemorrágica aguda na infância discutindo o desafio do diagnóstico. Paciente do sexo masculino, 8 anos, internado para investigação diagnóstica. Apresentava anemia grave associada a febre e trombose das veias cavas superior e inferior, por isso prescreveu-se enoxaparina. A hipótese diagnóstica foi de linfoma anaplásico de grandes células. Após 20 dias da administração do anticoagulante o paciente desenvolveu epistaxe seguida de formação de trombo hemorrágico oral em lábio superior e inferior. Um protocolo específico de cuidados bucais envolveu a avaliação da equipe multiprofissional. Resultados: houve remissão da ferida com o restabelecimento físico e emocional. Conclusão: conforme protocolo individual de atendimento houve restabelecimento das funções vitais da cavidade oral: mastigação, deglutição, digestão, paladar, fala, resignificando o real significado do sorriso; crucial em pacientes oncohematológicos.

Palavras-chave: cavidade bucal, oncologia, trombose e pediatria.

ABSTRACT

Introduction: onco Hematological patients have an increased level of thrombosis and bleedings due to the treatment and the disease. Materials e Methods: To describe a case of an acute hemorrhagic edema of childhood discussing the challenge of diagnostic. Male, 8 years old, hospitalized for diagnostic investigation. There were severe anemia associated with fever and thrombosis of the superior and the inferior vena cava when was prescription of enoxaparin. The diagnostic hypothesis was large cell lymphoma. After 20 days of anticoagulant administration the patient developed epistaxis followed by the formation of oral hemorrhagic edema in the upper and lower lip. An specific protocol of oral care envolved the multiprofessional team assessment. Results: there was remission of the wound strengthened with the physical and emotional reestablishment. Conclusion: according individual protocol of care there were reestablishment of the vital function of the oral cavity:chewing, swallowing, digestion, taste, speech, re-imagining the real meaning of the smile; crucial in oncohematological patientes.

Key-words: oral cavity, oncology, thrombosis and pediatrics.

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	OBJETIVO

1 INTRODUÇÃO

Os linfomas podem ser classificados em Hodgkin ou não-Hodgkin, podendo afetar células B ou T (MUGNAINI e GHOSH, 2016). No caso do linfoma anaplásico de grandes células (ALCL) é caracterizado pela proliferação de células T e é classificado como um linfoma não-Hodgkin, podendo ser ALK-positivo ou ALK-negativo (TSUYAMA et al., 2017). Nos pacientes pediátricos, é mais comum o desenvolvimento da forma ALK-positiva e representa 10 a 30% dos linfomas sendo mais predominante no sexo masculino. Vários fatores estão associados ao aparecimento da doença (MUGNAINI e GHOSH, 2016; TSUYAMA, et al., 2017). As manifestações clínicas incluem: linfadenopatia periférica podendo ser mediastinal, abdominal ou cervical, envolvimento extranodal da pele, osso e tecidos moles, inclusive sistema nervoso central e rins. Podem ocorrer ainda trombocitopenia, fadiga e palidez decorrentes da anemia (TSUYAMA et al., 2017; DE ANDRADE et al., 2020). As manifestações bucais são raras, mas podem se manifestar como uma massa hemorrágica ulcerada em rebordo alveolar, palato, língua e lábio (DE ANDRADE et al., 2020). Em relação às manifestações bucais decorrentes do tratamento oncológico podem-se incluir mucosite, xerostomia, infecções oportunistas, inflamação e lesões cariosas (RITWIK, 2018).

O tratamento do ALCL envolve associação de multiagentes quimioterápicos, inclusive uso de antracíclicos. Várias associações são propostas, incluindo CHOP (ciclofosfamida, doxorrubicina, vincristina e prednisona) com etoposídeo. Para casos de reincidência é realizado outras terapias, por exemplo, ICE (ifosfamida, etoposídeo, carboplatina) e DHAP (dexametasona, cisplatina, citarabina em alta dose) (CHIHARA e FANALE, 2017; SHUSTOV e SOMA, 2019). Além do tratamento específico faz-se necessário um acompanhamento a longo prazo para monitorar possíveis complicações decorrentes do tratamento antineoplásico, como: síndrome de lise tumoral, infecção, trombose, pancreatite, neoplasia secundária, distúrbio cognitivo e endocrinopatia (HOUGH e VORA, 2017). Essas complicações estão associadas a maior morbidade do doente, afetam a qualidade de vida do paciente quando comparada à de sua família, apresentando comprometimento psicológico durante o tratamento (FARDELL et al., 2017).

Uma das complicações recorrentes nesses pacientes é o tromboembolismo venoso, gerando uma trombocitose pré quimioterapia, o que mostra uma possível influência tumoral na função plaquetária. Tais fatores evidenciam uma dúvida sobre qual é a contribuição das plaquetas para o desenvolvimento do tumor (YAN e JURASZ, 2016). Além disso, a quimioterapia também tem relação com a alteração dos fatores de coagulação que resulta em hipercoagulabilidade induzindo condição pró-trombótica (SHEGAL et al., 2017).

Assim, para o tratamento e/ou profilaxia das tromboses as diretrizes atuais indicam a heparina de baixo peso molecular. Embora tenha um prognóstico favorável comprovado, os anticoagulantes podem estar associados a um aumento do risco de sangramentos (LYMAN et al., 2015; STREIFF et al., 2018). Os anticoagulantes orais diretos são aprovados para o tratamento da trombose, no entanto ainda não existem muitos estudos sobre a aplicação desse medicamento em pacientes oncológicos, principalmente, pediátricos (LYMAN et al., 2015; STREIFF et al., 2018; DAMLE et al., 2021).

Diante das complicações causadas pela quimioterapia nos fatores de coagulação e suas repercussões na cavidade bucal, apresentamos um caso infrequente de um paciente portador de ALCL, que desenvolveu uma lesão hemorrágica extensa em ambos os lábios durante a administração de anticoagulantes orais e quimioterápicos e a conduta terapêutica odontológica junto a equipe multiprofissional.

2 OBJETIVO

O presente estudo tem como objetivo discutir, através de um relato de caso, uma lesão hemorrágica grave, expondo seus aspectos clínicos, sintomatologia, manejo e tratamento, além de possível interferência no tratamento antineoplásico.

3 ARTIGO CIENTÍFICO

O manuscrito apresentado nessa seção seguiu as instruções aos autores da *Special Care in Dentistry*, classificada no Qualis da CAPES (Coordenação de Aperfeiçoamento do Pessoal de Nível Superior), na Área de Avaliação de Odontologia, como B2.

Diagnostic and therapeutic pathways of lip lesions in onco hematology: report of a challenging pediatric case

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ABSTRACT

Introduction: Onco Hematological patients have an increased level of thrombosis and bleedings due to the treatment and the disease. Materials e Methods: To describe a case of an acute hemorrhagic edema of childhood discussing the challenge of diagnostic. Male, 8 years old, hospitalized for diagnostic investigation. There were severe anemia associated with fever and thrombosis of the superior and the inferior vena cava when was prescription of enoxaparin. The diagnostic hypothesis was large cell lymphoma. After 20 days of anticoagulant administration the patient developed epistaxis followed by the formation of oral hemorrhagic edema in the upper and lower lip. An specific protocol of oral care envolved the multiprofessional team assessment. Results: There was remission of the wound strengthened with the physical and emotional reestablishment. Conclusion: According individual protocol of care there were reestablishment of the vital function of the oral cavity:chewing, swallowing, digestion, taste, speech, re-imagining the real meaning of the smile; crucial in oncohematological patientes.

Key-words: oral cavity, oncology, thrombosis and pediatrics.

INTRODUCTION

Lymphomas can be classified in Hodgkin or non-Hodgkin affecting B-cells or T-cells¹. The anaplastic large cell lymphoma (ALCL) is characterized by the malignant proliferation of T-cells and is classified as a non-Hodgkin lymphoma, that can be ALK-positive or ALK-negative². In the pediatric patient it is more common the development of the ALK-positive type and represents 10-30% of lymphomas prevailing on the male gender. Multiple factors are associated with the emergence of this disease¹,². Clinical manifestations include: peripheral lymphadenopathy (that can be mediastinal, abdominal or cervical), with extranodal involvement of skin, bones and soft tissues, including the central nervous system and kidneys. It is also possible to occur thrombocytopenia, fatigue and paleness consequential to the anemia²,³. Oral cavity manifestations are rare, although it can happen as an ulcerated and hemorrhagic mass in the regions of alveolar ridge, palate, tongue and lips³. Regarding the oral cavity manifestations arising from the oncologic treatment there can be mucositis, xerostomia, opportunistic infections, inflammation e carious lesions⁴.

The treatment of ALCL involves the association of multi-agents of chemotherapeutic drugs, including the use of anthracyclines. A variety of associations have been suggested including CHOP (cyclophosphamide, doxorubicin hydrochloride, vincristine sulfate and prednisone) with etoposide. In cases of cancer recurrence other therapies can be done, for example, ICE (ifosfamide, carboplatin, and etoposide) e DHAP (dexamethasone, high dose Ara C, known as cytarabine, and cisplatin)^{5,6}. Besides the specific treatment, a long-term follow up is needed to monitor possible complications from the antineoplastic therapy, such as: tumor lysis syndrome, infection, thrombosis, pancreatitis, secondary neoplasm, cognitive dysfunction e endocrinopathy ⁷. These complications are related to higher patient morbidity, affecting the patients quality of life, displaying psychological impairment during treatment ⁸.

A recurrent complication in these patients is the venous thromboembolism, triggering a pre-chemotherapy thrombocytosis, that shows a possible tumoral influence in the platelet function. Those factors uncover a doubt over the contribution of the platelets on tumor development ⁹. Moreover, chemotherapy also has a correlation to the clotting factors alterations resulting in hypercoagulability inducing a prothrombotic state¹⁰.

Therefore, for the treatment and/or prophylaxis of thrombosis the current guidelines recommend the low molecular weight heparin. Even though having a

favorable prognosis, anticoagulants can be associated to a higher risk of bleedings^{11,12}. The direct oral anticoagulants are approved for thrombosis treatment however there aren't many studies about the applicability of this drug in oncologic patients especially the pediatrics ones¹¹⁻¹³.

Facing the complications caused by chemotherapy on the clotting factors and its repercussions on the oral cavity, we bring forward an infrequent case of a ALCL patient that developed an extensive hemorrhagic wound in both lips during the administration of oral anticoagulants and chemotherapeutic agents and also the therapeutic conduct of the dental team bonded with the multiprofessional team.

CASE REPORT

Male, 8 years old, admitted for hospitalization in a regional reference hospital in the city of Juiz de Fora - Brazil, for diagnosis investigation. The main reason for the hospitalization was a severe anemia, fever and thrombosis of the superior and the inferior vena cava. The immediate therapeutic intervention was enoxaparin. The diagnostic hypothesis was anaplastic large cell lymphoma. This study was approved by the Ethics Committee of the Universidade Federal de Juiz de Fora under the protocol number 3.294.048.

Twelve days after beginning the anticoagulant the patient developed an hemorrhagic wound in the upper and lower lip (Figure 1).



Figure 1: Initial clinical aspects of the lip thrombus on the first appointment.

The opinion of the dental team was required. During the physical examination it was confirmed the presence of a hemorrhagic bluish-reddish wound in both lips associated with dehydration and paleness of the lip. There was also an

increased degree of cutaneous dehydration related to epithelial squamation and discrete epistaxis. Furthermore, fungal infections in the labial commissure region was noticed. The patient and its caregiver reported the dry lips and the habit of the patient to traumatize the epithelial squamation with his teeth and to lick the lips. The patient refused to eat and presented an important deficit to the general well being. After discussing the clinical case with the medical team and analyzing the oral hemorrhagic complications it was decided to reduce the anticoagulant dose from 60 mg/ml to 40 mg/ml and move forward with the wound debridement.

The procedure included lip humidification with physiological saline solution and subsequent debridement of the thrombus under topical anesthesia with benzocaine. The patient did not displayed heavy bleeding which was tamponaded with local compression with sterile gauze soaked in physiological saline solution. After the rigorous debridement, the photodynamic therapy (Photon Lase III - PL7336, DMC) therapy took place at an inclination angle of 90 degrees in respect of an lip contact area (660 nm, 50 mW, 4 J / cm 2, 90 seconds) punctually in the wound area.

To control fungal infections in the labial commissure region it was prescribed topic nystatin. In addiction, alpha-tocopherol acetate (vitamin E) due the antioxidant and hydrating mechanism was indicated.

The patient followed the treatment with the photodynamic therapy applications spaced at every 48 hours (Figure 2 and 3), with all other medications maintained. After 15 days of establishment of the dental interventions and the dose adjustment of the anticoagulant, there was total remission of the wound strengthened with the physical and emotional reestablishment of the patient (Figure 4).



Figure 2 – Clinical aspects after 3 sections of odontological care.



Figure 3 – Clinical aspects after 6 sections of odontological care.



Figure 4 – Clinical aspects after the completion of the case.

DISCUSSION

The greatest importance of this case report is to emphasize the defiant strategy of approach of a patient with anaplastic large cell lymphoma with hemorrhagic orofacial complications related to the anticoagulant drug therapy. The hemorrhagic and extensive wound in both lips, besides being painful also had repercussions in nutrition and general well being of the patient, masking a local fungus infection. It is a infrequent case, scarce in the scientific literature in the specific profile of a pediatric oncology patient. These oral clinical findings can interfere in the prognosis of a severe disease, like the ALCL, and can contribute to spreading the orofacial care strategy.

The hospitalization occurred as a result of severe anemia associated to fever and thrombosis of the superior and the inferior vena cava. These clinical findings can be representative of a lymphoma, due to the immunological imbalance^{2,3}. After 12 days since the introduction of the anticoagulant therapy, the patient developed an oral

hemorrhagic wound on the lips and an epistaxis. According to the scientific literature, only 5 other cases were reported about wounds with simmilant clinical aspects but with different etiologies. The wound described in this paper has its etiology related to anticoagulation whereas the others lesions related in previous studies had the opposite etiology, meaning they were related to thrombus¹⁴⁻¹⁸. There are scarce scientific data regarding this lesion in this specific ALCL patient profile as presented here.

Following the oral manifestation, the dental team, after a systematic clinical exame, observed clinical signs of epistaxis that corroborated the diagnosis of the hemorrhagic lip wound as a hemorrhagic wound possibly related to anticoagulation ¹⁹⁻²³. The patient also presented fungal infections in the labial commissure region that can be explained by a degree of immunosuppression due to the ALCL ⁴.

In the face of those lip lesions, was performed the debridement hemorrhagic crust and necrotic tissue with the use of benzocaine topical anesthesia²⁴ and photodynamic therapy in order to improve cicatrization and tissue regeneration²⁵. Regarding the fungal infection, it was prescribed topic nistatin²⁶. Moreover the vitamin E was prescribed with the means to provide an antioxidant action and hydrate the lips²⁷.

The limitation of this case-report lies in the scarcity of similar clinical conditions.

Therefore after the protocol of oral care there was total remission of the lesions with substantial clinical repercussions. There were reestablishment of the patients nutrition and physical and emotional well-being associated to pain relief. The description of this case helps the team involved in the care of the oncohematologic patients in the diagnostic approach and in the decision-making process.

CONCLUSION

This case-report highlight the therapeutic challenge of the oral complications in pediatric oncology. The approach based on the cross-disciplinary action, a judicious clinical examination, the harvesting of the medical history of the disease, the gathering of the information in the patient's records and the deep evaluation of the complementary laboratory exams were all determinants to an effective take. Thus strengthening the concept of orofacial care based on the individual and not on the disease. Therefore, the dental treatment based on scientific evidences and patients singularity contributed to a better prognosis and to the reestablishment of

the vital function of the oral cavity: chewing, swallowing, digestion, sense of taste, speech⁴ re-imagining the real meaning of the smile.

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4 CONCLUSÃO

Este relato de caso evidencia o desafio terapêutico das complicações odontológicas em oncopediatria. A abordagem baseada na atuação interdisciplinar, exame clínico criterioso, obtenção da história médica atual e das informações do prontuário médico juntamente com a avaliação dos exames laboratoriais complementares foram determinantes para uma atuação efetiva. Assim, consolidam os fundamentos da odontologia baseada na pessoa e não na doença. Desta forma, o tratamento odontológico baseado em evidências e nas especificidades do paciente, contribui para o melhor prognóstico do doente e restabelece as funções vitais da cavidade bucal: mastigação, deglutição, digestão, paladar, fala (RITWIK, 2018) ressignificando o verdadeiro valor do sorriso.

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ANEXO A – Normas para publicação do periódico

1. SUBMISSION

Authors should kindly note that submission implies that the content has not been published or submitted for publication elsewhere except as a brief abstract in the proceedings of a scientific meeting or symposium.

1. Submission and Peer Review Process

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The mission of *Special Care in Dentistry* is to provide a forum for research findings, case reports, clinical techniques, and scholarly discussion relevant to the oral health and oral health care of patients with special needs. The designation of the patient with special needs is not limited to hospitalized, disabled or older individuals, but includes all patients with special needs for whom oral health and oral health care are complicated by physical, emotional, financial and/or access factors.

3. MANUSCRIPT CATEGORIES AND REQUIREMENTS

- **Original Papers** reports of new research findings or conceptual analyses that make a significant contribution to knowledge (3500 word limit).
- Review articles articles of special interest and those entailing an update on any of the topics identified as subjects for this journal will be considered (3500 word limit).
- Systematic review articles systematic review is a review of published literature addressing a specific research question. It should include an exhaustive search of the literature to date. The search strategy used should be reported within the paper. The authors should define eligibility criteria for included studies a priori, and describe these. There should be evidence of independent judging of study eligibility, performed by at least two authors, with the degree of agreement between authors described. Data extraction from individual studies should also be performed in duplicate, and there should be evidence that any differences in data extraction were discussed between authors,

The reporting of systematic reviews should adhere to the PRISMA statement –

(for further information please see section below under ETHICS). Further guidance is also available from the Cochrane organisation's "Reviewer's Handbook".

- Case History Report case reports should be concise and do not need to be as formally structured as scientific articles. Include a brief introduction presenting a critical literature review and a statement of the clinical implications of the case. The case description should include: personal history of the subject, socioeconomic data, health/medications history, extra-oral and intra-oral examination findings; differential diagnosis; treatment options; final treatment plan. Relevant techniques, results and data obtained should be presented. A brief discussion should reinforce the clinical implications of the case report and discuss any unique findings and insights gained, which makes this patient or patients different from any patients previously reported (2500 word limit; In addition, there is a limit of a total of 4 figures or 4 tables)
- Letters to the Editor are welcomed (1000 word limit and 1 figure/table; Letters to the Editor should not have an abstract).

4. PREPARING YOUR SUBMISSION

Special Care in Dentistry now offers Free Format submission for a simplified and streamlined submission process.

Manuscripts can be uploaded either as a single document (containing the main text, tables and figures), or with figures and tables provided as separate files. Should your manuscript reach revision stage, figures and tables must be provided as separate files. The main manuscript file can be submitted in Microsoft Word (.doc or .docx

Your main document file should include:

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- The full names of the authors with institutional affiliations where the work was conducted, with a footnote for the author's present address if different from where the work was conducted;
- Acknowledgments:
- Abstract structured (intro/methods/results/conclusion) or unstructured;
- Up to seven keywords;
- Main body: formatted as introduction, materials & methods, results, discussion, conclusion;
- References:
- Tables (each table complete with title and footnotes);
- Figures: Figure legends must be added beneath each individual image during upload AND as a complete list in the text.

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If you are invited to revise your manuscript after peer review, the journal will also request the revised manuscript to be formatted according to journal requirements as described below.

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Conflict of Interest Statement

Authors will be asked to provide a conflict of interest statement during the submission process. For details on what to include in this section, see the 'Conflict of Interest' section in the Editorial Policies and Ethical Considerations section below. Submitting authors should ensure they liaise with all co-authors to confirm agreement with the final statement.

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Abstract

The Abstract should be divided into the following sections: 'Aims', 'Methods and Results', and 'Conclusion'; it should not exceed 200 words.

Keywords

Key words should be selected from Medical Subject Headings (MeSH) to be used for indexing of articles

Main Text

- As papers are double-blind peer reviewed, the main text file should not include any information that might identify the authors.
- Original Articles and Brief Communications are normally organized with Introduction, Material and Methods, Results and Discussion sections, but authors should consult recent journal issues for acceptable alternative organizations.
- The manuscript should be submitted with all material doublespaced, flush left (preferably in Courier typeface), with at least a 1" margin all around. All pages

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All references should be numbered consecutively in order of appearance and should be as complete as possible. In text citations should be superscript numbers. Journal titles are abbreviated; abbreviations may be found in the following: MEDLINE, Index Medicus, or CalTech Library.

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Sample references follow:

Journal article

Wood WG, Eckert GP, Igbavboa U, Muller WE. Statins and neuroprotection: a prescription to move the field forward. Ann N Y Acad Sci 2010; 1199:69-76.

Book

Hoppert, M. Microscopic techniques in biotechnology. Weinheim: Wiley-VCH; 2003.

Electronic Material

Cancer-Pain.org [homepage on the internet]. New York: Association of Cancer Online Resources, Inc.; c2000–01 [Cited 2015 May 11]. Available from: http://www.cancer-pain.org/.

Tables

Tables should be self-contained and complement, not duplicate, information contained in the text. They should be supplied as editable files, not pasted as images. Legends should be concise but comprehensive – the table, legend, and footnotes must be understandable without reference to the text. All abbreviations must be defined in footnotes. Footnote symbols: \uparrow , \downarrow , \S , \P , should be used (in that order) and * , ** , *** should be reserved for P-values. Statistical measures such as SD or SEM should be identified in the headings.

Figure Legends

Legends should be concise but comprehensive – the figure and its legend must be understandable without reference to the text. Include definitions of any symbols used and define/explain all abbreviations and units of measurement.

Figures

Although authors are encouraged to send the highest-quality figures possible, for peerreview purposes, a wide variety of formats, sizes, and resolutions are accepted. **Click here** for the basic figure requirements for figures submitted with manuscripts for initial peer review, as well as the more detailed post-acceptance figure requirements.

Figures submitted in color will be reproduced in color online free of charge.

Additional Files

Appendices

Appendices will be published after the references. For submission they should be supplied as separate files but referred to in the text.

Supporting Information

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For manuscripts reporting medical studies that involve human participants, a statement identifying the ethics committee that approved the study and/or confirmation that the study conforms to recognized standards is required, for example: Declaration of Helsinki; US Federal Policy for the Protection of Human Subjects; or European Medicines Agency Guidelines for Good Clinical Practice.

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UK authors should conform to UK legislation under the **Animals (Scientific Procedures) Act 1986 Amendment Regulations (SI 2012/3039)**.

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ANEXO B – Parecer do Comitê de Ética em Pesquisa



PARECER CONSUBSTANCIADO DO CEP

DADOS DA EMENDA

Título da Pesquisa: Implicações dos cuidados odontológicos em oncopediatria

Pesquisador: Gisele Maria Campos Fabri

Área Temática: Versão: 5

CAAE: 59668316.3.0000.5147

Instituição Proponente: FACULDADE DE ODONTOLOGIA

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 3.294.048

Apresentação do Projeto:

Trata-se de projeto de pesquisa destinado a averiguar implicações de cuidados

odontológicos em oncopediatria. Depois de aprovada uma primeira emenda, retorna a este CEP com proposta de nova emenda dilatando o prazo e propondo mudanças na equipe pelas razões que apresenta.

Apresentação do projeto esta clara, detalhada de forma objetiva, descreve

as bases científicas que justificam o estudo, de acordo com as disposições definidas na Resolução CNS 466/12 de 2012, item III.a.

Objetivo da Pesquisa:

Os objetivos estão em consonância com os propósitos gerais da pesquisa, está bem delineado, apresenta clareza e compatibilidade com a proposta, tendo adequação da metodologia aos objetivos pretendido, de acordo com o que dispõe a Norma Operacional CNS 001 de 2013, item 3.4.1 - 4.

Avaliação dos Riscos e Benefícios:

O projeto descreve adequadamente os riscos como maiores que mínimos, em virtude de os participantes estarem em tratamento com imunossupressores. Identificação dos riscos e as possibilidades de desconfortos e benefícios esperados estão adequadamente descritos.

A avaliação dos Riscos e Benefícios está de acordo com as disposições definidas na Resolução CNS 466/12 de 2012, itens III; III.2 e V.

Endereço: JOSE LOURENCO KELMER S/N

Bairro: SAO PEDRO CEP: 36.036-900

Município: JUIZ DE FORA UF: MG

Fax: (32)1102-3788 Telefone: (32)2102-3788 E-mail: cep.propesq@ufjf.edu.br



Comentários e Considerações sobre a Pesquisa:

A metodologia atende ao(s) objetivo(s) proposto(s) e informa:

- · tipo de estudo;
- · procedimentos que serão utilizados
- apenas o número de participantes que irá receber a intervenção terapêutica é citado; número de participantes que irão traduzir o material escrito não é citado
- critérios de inclusão e exclusão
- · forma de recrutamento, abordagem e consentimento livre e esclarecido
- · modo de coleta de dados
- · tipo de análise
- · cuidados éticos
- Com relação aos participantes da tradução do material escrito, faltam informações sobre número de participantes, critérios de inclusão e exclusão, forma de recrutamento, abordagem e obtenção do consentimento livre e esclarecido
- As referências bibliográficas são atuais, sustentam os objetivos do estudo e seguem uma normatização
 O cronograma mostra
- o agendamento das diversas etapas da pesquisa, tendo já iniciado a etapa de recrutamento doa participantes – o que indica a reprovação automática do projeto
- Não informa que a coleta de dados ocorrerá após aprovação do projeto pelo comitê

O orçamento

- · lista a relação detalhada dos custos da pesquisa
- · apresenta o responsável pelo financiamento

O instrumento de coleta de dados é pertinente aos objetivos delineados e preserva o participante do constrangimento

O TCLE

- Está em linguagem adequada, clara para compreensão do sparticipante, no TCLE (1); os outros 2 estão em linguagem de difícil compreensão para os participantes aos quais se destinam
- · Apresenta justificativa e objetivos
- · Descreve suficientemente os procedimentos
- · Apresenta campo para a identificação dos participantes
- Informa que uma das vias do TCLE deverá ser entregue ao participante
- · Assegura liberdade do participante recusar ou retirar o consentimento sem penalidades

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- Explicita
- o Ressarcimento de despesas
- o Indenização diante de eventuais danos decorrentes da pesquisa
- o Forma de contato com o pesquisador
- o Forma de contato com o CEP
- o Como será o descarte de material coletado (no caso de material biológico)
- o O arquivamento do material coletado pelo período mínimo de 5 anos
- o Descrição parcial dos riscos e desconfortos esperados

Considerações sobre os Termos de apresentação obrigatória:

O protocolo de pesquisa está em configuração adequada, apresenta FOLHA DE ROSTO devidamente preenchida, com o título em português, identifica o patrocinador pela pesquisa, estando de acordo com asdisposições definidas na Norma Operacional CNS 001 de 2013 item 3.3 letra a; e 3.4.1 item 16. Apresenta oS TERMO DE CONSENTIMENTO E DE ASSENTIMENTO LIVRE E ESCLARECIDO. A pesquisadora apresenta titulação e experiência compatível com o projeto de pesquisa, estando de acordo com o disposto no Manual Operacional para CEPs. Apresenta DECLARAÇÃO de infraestrutura e de concordância com a realização da pesquisa de acordo com o que se prevê na Norma Operacional CNS 001 de 2013 item 3.3 letra h.

Recomendações:

Apesar da relevância do projeto e das razões da emenda, reforça-se a orientação à pesquisadora no sentido de atender às seguintes inadequações:

- 1. As modificações introduzidas pela emenda devem ser apresentadas em destaque no Projeto Detalhado;
- 2. Apesar da orientação em parecer anterior, a linguagem empregada nos termos de consentimento e assentimento, em especial no Termo de assentimento do menor, mantém passagens de difícil acesso ao entendimento, como "possíveis implicações odontológicas" ou "protocolos de cuidados odontológicos";
- 3. Apesar da orientação de pareceres anteriores, a pesquisadora exime-se de nomear adequadamente como câncer a doença de que padece o participante que, por sua vez, não deve ser chamado de paciente, por não ser esta a denominação que define seu estatuto na pesquisa.

Endereço: JOSE LOURENCO KELMER S/N

Bairro: SAO PEDRO CEP: 36.036-900

UF: MG Município: JUIZ DE FORA



Conclusões ou Pendências e Lista de Inadequações:

Diante do exposto, a emenda ao projeto está aprovada, com a ressalva de ser imprescindível o atendimento às recomendações acima. Data prevista para o término da pesquisa:fevereiro de 2021.

Considerações Finais a critério do CEP:

Diante do exposto, o Comitê de Ética em Pesquisa CEP/UFJF, de acordo com as atribuições definidas na Res. CNS 466/12 e com a Norma Operacional Nº001/2013 CNS, manifesta-se pela APROVAÇÃO a emenda do protocolo de pesquisa proposto. Vale lembrar ao pesquisador responsável pelo projeto, o compromisso de envio ao CEP de relatórios parciais e/ou total de sua pesquisa informando o andamento da mesma, comunicando também eventos adversos e eventuais modificações no protocolo.

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_133260 1 E2.pdf	09/04/2019 14:19:13		Aceito
Outros	solicitacaodeprorrogacao2.doc	09/04/2019 14:15:14	IASMINY SOARES DE OLIVEIRA	Aceito
Projeto Detalhado / Brochura Investigador	projetodetalhado2.doc	09/04/2019 14:14:58	IASMINY SOARES DE OLIVEIRA	Aceito
Cronograma	cronograma2.docx	09/04/2019 14:14:39	IASMINY SOARES DE OLIVEIRA	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLE2mod.doc	26/12/2016 14:25:24	IASMINY SOARES DE OLIVEIRA	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	assentimento2mod.doc	26/12/2016 14:25:05	IASMINY SOARES DE OLIVEIRA	Aceito
Folha de Rosto	folha.pdf	02/09/2016 14:40:10	IASMINY SOARES DE OLIVEIRA	Aceito
Declaração de Instituição e Infraestrutura	infraestrutura.pdf	01/09/2016 18:15:24	IASMINY SOARES DE OLIVEIRA	Aceito
Orçamento	orcamento.docx	01/09/2016 18:01:27	IASMINY SOARES DE OLIVEIRA	Aceito

Endereço: JOSE LOURENCO KELMER S/N

CEP: 36.036-900 Bairro: SAO PEDRO

UF: MG Município: JUIZ DE FORA

Fax: (32)1102-3788 Telefone: (32)2102-3788 E-mail: cep.propesq@ufjf.edu.br



Situação do Parecer:

Aprovado

Necessita Apreciação da CONEP:

Não

JUIZ DE FORA, 30 de Abril de 2019

Assinado por: Jubel Barreto (Coordenador(a))

Endereço: JOSE LOURENCO KELMER S/N

Bairro: SAO PEDRO CEP: 36.036-900

UF: MG Município: JUIZ DE FORA

Telefone: (32)2102-3788 Fax: (32)1102-3788 E-mail: cep.propesq@ufjf.edu.br

ANEXO C - Certificado de apresentação de painel no 38° CIOSP (Congresso Internacional de Odontologia de São Paulo)



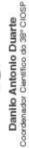
CERTIFICADO

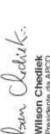
Certificamos que o trabalho na categoria PAINEL - PAI-506 - TRATAMENTO DE TROMBO LABIAL GRAVE EM PACIENTE ONCOHEMATOLÓGICO: RELATO DE CASO, foi apresentado no dia

01/02/2020, pelo(s) autor(es):

IASMINY SOARES DE OLIVEIRA GISELE MARIA CAMPOS FABRI TEREZA CRISTINA ESTEVES VICTORIA BOECHAT FEYO









ANEXO D – Certificado de apresentação de trabalho no 17° Congresso Sabincor de Cardiologia



ANEXO E – Certificado de apresentação de pôster na I Jornada de Oncologia e Patologia da Zona da Mata Mineira



ANEXO F - Comprovante de submissão na revista Special Care in Dentistry



16-Feb-2023

Dear Dr. Feyo:

Your manuscript entitled "Diagnostic and therapeutic pathways of lip lesions in onco hematology: report of a challenging pediatric case" by Feyo, Victória Boëchat; Oliveira, Iasminy; Fabri, Júlia Campos; Esteves, Tereza Cristina; Chaves, Maria das Graças; Fabri, Gisele Maria Campos, has been successfully submitted online and is presently being given full consideration for publication in Special Care in Dentistry.

Co-authors: Please contact the Editorial Office as soon as possible if you disagree with being listed as a co-author for this manuscript.

Your manuscript ID is 4742.

You can view the status of your manuscript at any time by logging into the submission site at wiley.atyponrex.com/journal/SCD.

Thank you for submitting your manuscript to Special Care in Dentistry.

Sincerely, Special Care in Dentistry Editorial Office