

Plan Overview

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Title: Paromomycin for the treatment of tegumentary leishmaniasis: investigation in vitro, in vivo and in the identification of molecular markers associated with susceptibility and resistance

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Project abstract:

Leishmaniasis is a parasitic disease with wide geographic distribution in Brazil with an increased number of cases in urban areas in recent years. The current state of treatment of different clinical forms of leishmaniasis is one of the critical areas in the management of this disease, since the drugs used require parenteral use, are costly and induce side effects. The available drugs used in Brazil are limited to pentavalent antimony, amphotericin B and pentamidine. In the last years, two drugs have been approved as alternatives to the treatment of visceral leishmaniasis in Asia: miltefosine and paromomycin. In this scenario, we propose to evaluate in this study the susceptibility *in vitro* to paromomycin in clinical isolates of *Leishmania* spp. from patients of the State of São Paulo and dogs from the city of Embu-Guaçu, as well as its efficacy *in vivo* in experimental models of infection with species responsible for tegumentary leishmaniasis in Brazil. We also propose to characterize molecularly parasites resistant to paromomycin selected *in vitro*, in order to identify potential genes linked to susceptibility and resistance to paromomycin. Once identified, genes will be functionally validated using strategies of genetic manipulation of the parasite. This study will assess the potential use of paromomycin for the treatment of leishmaniasis in Brazil and contribute to a better understanding of the mechanism of action and resistance to paromomycin that are not completely

understood, despite its high clinical efficacy against visceral leishmaniasis.

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Paromomycin for the treatment of tegumentary leishmaniasis: investigation in vitro, in vivo and in the identification of molecular markers associated with susceptibility and resistance

Coleta de Dados

Que dados serão coletados ou criados?

- 1) Isolates from humans and dogs of the parasite of the genus *Leishmania*.
- 2) Drug resistant lines selected *in vitro* of the parasite of the genus *Leishmania*.
- 3) Transgenic lines of the parasite of the genus *Leishmania*.
- 4) DNA sequences from ITS (internal transcribed spacer) of isolates of *Leishmania*.
- 5) Whole genome sequences of clinical isolates and drug resistant lines of the parasite of the genus *Leishmania*.
- 6) Drug susceptibility assays *in vitro* and *in vivo* against the parasite of the genus *Leishmania*.

Como os dados serão coletados ou criados?

- 1) Isolates of *Leishmania* sp. are obtained from patients and dogs.
- 2) Transgenic lines are generated using molecular genetic technology.
- 3) Drug susceptibility assays are conducted by colorimetric methods and/or counting.
- 4) DNA sequence analyses are conducted with individual DNA extractions followed by Illumina sequencing and/or Sanger sequencing.

Documentação e Metadados

Que documentação e metadados acompanharão os dados?

All data will be made publicly available after publication. At this point the data may be used in meta-analyses with the caveat of full citation.

Ética e Conformidade Legal

Como você administrará qualquer questão ética?

This research does not involve human participants.

Como você vai gerenciar os direitos autorais e os direitos de propriedade intelectual (IP / IPR)?

There is no copyright and IPR of any generated data.

Armazenamento e Backup

Como os dados serão armazenados e terão backup durante a pesquisa?

- 1) Isolates and transgenic lines of *Leishmania* sp. are stored at -150 °C in the facilities of the Department of Animal Biology of Institute of Biology, UNICAMP. Replicates are also stored in a -80oC freezer.
- 2) The primary and processed DNA sequences, and drug susceptibility data originated from the project are stored on personal computers and in an external hard disk that are backed-up through archive storage and supported by IT specialists. All data sets will be made freely available after publication.
- 3) Whole genome and DNA sequences data will be deposited in databases for public access, after publication.

Como você vai gerenciar o acesso e a segurança?

- 1) Isolates and transgenic lines are stored in secure facilities, in accordance with regulations concerning pathogenic materials, at the Department of Animal Biology of the Institute of Biology at UNICAMP.
- 2) Whole genome and DNA sequences will be stored in database after publication. No additional security is required.
- 3) There is a potential risk regarding the storage of the isolates and transgenic parasites in the liquid nitrogen container archives and freezer. This is mitigated by the security measures in place: locked doors and freezers.

Seleção e Preservação

Quais dados são de valor a longo prazo e devem ser mantidos, compartilhados e / ou preservados?

- 1) Isolates and transgenic lines of *Leishmania* spp.
- 2) Drug susceptibility assays data.
- 3) Whole genome sequences.

4) General DNA sequences of Leishmania spp.

Qual é o plano de preservação a longo prazo do conjunto de dados?

1) Isolates and transgenic lines of Leishmania sp. are stored at -150 °C in the facilities of the Department of Animal Biology of Institute of Biology, UNICAMP. Replicates are also stored in a -80oC freezer.

2) The primary and processed DNA sequences, and drug susceptibility data originated of the project are stored on personal computers and in an external hard disk that are backed-up through archive storage and supported by IT specialists. All data sets will be made freely available after publication.

3) Whole genome and DNA sequences data will be deposited in databases for public access, after publication.

Compartilhamento de Dados

Como você vai compartilhar os dados?

Beyond publication in internationally highly recognized peer-reviewed journals, all results will be disseminated through poster and oral presentations at national and international conferences. Publications will be deposited in the "Repositório da Produção Científica e Intelectual da UNICAMP (<http://www.repositorio.unicamp.br/>).

The main investigator will coordinate requests for access, committed to the principles of open science.

Existem restrições ao compartilhamento de dados requeridos?

There is no restriction for data sharing.

Responsabilidades e Recursos

Quem será responsável pelo gerenciamento de dados?

Prof. Adriano C. Coelho

Quais recursos você precisará para entregar seu plano?

Funding is need to storage costs of isolates and transgenic lines of Leishmania spp., and for preparing/generating data for deposit.

Planned Research Outputs

Dataset - "Drug susceptibility of strains and isolates of Leishmania spp."

In vitro activity of drugs used in the chemotherapy of Leishmaniasis against strains and isolates of Leishmania spp. endemic in Brazil.

Dataset - "Whole genome and DNA sequences of strains, isolates and drug resistant lines of Leishmania spp."

Complete genome sequence and other specific DNA sequences of strains, isolates and drug resistant lines of Leishmania spp.

Planned research output details

Title	Type	Anticipated release date	Initial access level	Intended repository(ies)	Anticipated file size	License	Metadata standard(s)	May contain sensitive data?	May contain PII?
Drug susceptibility of strains and isolates of Lei ...	Dataset	2022-01-30	Open	None specified		None specified	None specified	No	No
Whole genome and DNA sequences of strains, isolate ...	Dataset	2022-01-30	Open	None specified		None specified	None specified	No	No