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Implementation of a culturally tailored decentralization programme for snakebite treatment in indigenous communities in the Brazilian Amazon

Submission date
12/03/2025

Recruitment status
Recruiting

Registration date
04/04/2025

Overall study status
Ongoing

Last Edited
04/04/2025

Condition category
Injury, Occupational Diseases, Poisoning

[X] Prospectively registered
[_] Protocol
[X] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study aims to adapt a program for treating snakebites with antivenom in indigenous communities in the Brazilian Amazon. The goal is to make the treatment safe, effective, and culturally appropriate for these communities. The program, called AJURI, was created because there is a growing need for antivenom therapy in these areas.

Who can participate?
The study will involve people from seven Special Indigenous Health Districts in the state of Amazonas, Brazil. This includes about 250,000 people from around 100 different ethnic groups.

What does the study involve?
Participants will be involved in different phases of the study. In the first phase, researchers will work with indigenous healers, community agents, health professionals, and leaders to adapt the antivenom therapy program. In the second phase, the program will be tested to see if it is feasible, acceptable, and culturally appropriate. Participants will include 50 indigenous health professionals and 50 community members.

What are the possible benefits and risks of participating?
The benefits of participating include improved access to antivenom therapy and better clinical outcomes for snakebite victims. Risks may include the challenges of adapting the program to different cultural practices and ensuring it is effective in all communities.

Where is the study run from?
Fundação de Medicina Tropical Dr. Heitor Vieira Dourado (FMT-HVD) (Brazil)
Liverpool School of Tropical Medicine (UK)
Duke University (USA)

When is the study starting and how long is it expected to run for?
August 2024 to July 2028.

Who is funding the study?
Medical Research Council (UK)

Who is the main contact?
Prof Wuelton M Monteiro, wueltonmm@gmail.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
MR/Y019709/1

Study information

Scientific Title
Implementation of a culturally tailored decentralization programme for snakebite treatment in indigenous communities in the Brazilian Amazon

Acronym
AJURI

Study objectives

The AJURI program, with culturally adapted materials and telehealth support for the CCSs, will enable the safe and effective decentralization of antivenom therapy for Indigenous communities, reducing treatment time and improving clinical and economic outcomes.
Implementation Hypothesis: AJURI will reduce the time to antivenom therapy compared to the centralized model.
Clinical Effectiveness Hypothesis: AJURI will promote better functional recovery post-SBE compared to conventional care.

Ethics approval required
Ethics approval required

Ethics approval(s)
submitted 27/11/2024, National Research Ethics Committee - CONEP (SRTV 701, Via W 5 Norte, lote D - Edifício PO 700, 5º andar – Asa Norte, Brasília, 70719-040, Brazil; +55 (61) 3315-5878; conep@saude.gov.br), ref: CAAE: 85053424.2.0000.0005

Study design
Community randomized trial

Primary study design
Interventional

Study type(s)
Other, Prevention, Quality of life, Treatment, Efficacy

Health condition(s) or problem(s) studied
Decentralized antivenom therapy program for Indigenous communities in the Brazilian Amazon affected by snakebites.

Interventions
The study will be conducted in seven Special Indigenous Health Districts (DSEIs) in the state of Amazonas, Brazil, covering about 250,000 people from approximately 100 ethnic groups, with a corresponding linguistic diversity. Most of these indigenous populations live in communities located in forested areas, where they engage in traditional subsistence activities such as fishing, hunting, gathering, and agriculture.

Phase 1 - Phases I and II: Qualitative Translation, Adaptation, and Co-Design: Under the guidance of Drs. Murta, Monteiro, and Vissoci, the research team, specialized in qualitative studies and co-design methodologies, will conduct iterative sessions with three working groups: indigenous healers and community agents; health professionals from the indigenous system; and local, state, and federal leaders of the indigenous health system, along with clinical experts and researchers in snakebite envenoming (SBEs). Phase III: Quantitative Implementation Targets: Aims to assess the feasibility, acceptability, linguistic clarity, congruence, and cultural appropriateness of the AJURI program developed in Phases I and II. For this phase, 50 indigenous health professionals, including clinical and non-clinical professionals, and 50 members of the indigenous community, including community agents, leaders, and healers, will be recruited. The selection of participants will be conducted by the working group leaders, and those selected will carry out a detailed evaluation of both the intervention package and the implementation strategy.

Phase 2 - Determining the Impact of AJURI Program Implementation on Time to Access Antivenom Therapy and Functionality: The aim of this phase is to evaluate the impact of the AJURI program implementation on indicators that may influence clinical outcomes. Participants will be included in the study from their first contact with the healthcare system, specifically in Community Health Centers (CCCs), and monitored to analyze the interval between the snakebite incident (SBI) and the administration of antivenom therapy (program implementation outcome), as well as the patient's functionality (clinical outcome). Throughout the implementation, communication with communities will be ongoing, establishing intercultural dialogue channels. Traditional healing practices will be respected and integrated into the antivenom therapy decentralization strategy, strengthening the program and preserving indigenous cultural knowledge. After each phase of the program, feedback sessions will be organized within the communities, where the obtained results will be presented and discussed. These sessions will allow for feedback collection and promote transparency. Communication will be adapted to the preferred formats of each community, including videos, audios, or written documents.

Intervention Type
Not Specified

Primary outcome(s)
Baseline characteristics
1. Sociodemographic information is measured using a sociodemographic survey at baseline
2. Severity of SBE is measured using Snakebite Severity Score at baseline
3. Time to care is measured using time of SBE to health care encounter and final care at baseline
Clinical care
4. Number of antivenom vials is measured using clinical report form at baseline
5. Time to achieve control is measured using clinical report form at baseline
6. Other medications are measured using clinical report form at baseline

Implementation outcomes
7. Time from SBE to antivenom is measured using self-reported time from SBE to antivenom at baseline, T1, T2, T3, T4, T5
8. Protocol deviations are measured using AJURI Adherence Scale at T2
9. Penetration and adaptations are measured using qualitative interviews with healthcare providers at T2
10. Sustainability and maintenance are measured using patient records and qualiative interviews with healthcare providers at T2

Clinical effectiveness outcomes
11. Patient functionality is measured using Patient Specific Functionality Scale at baseline, T1, T2, T3, T4, T5

Key secondary outcome(s))
1. All-cause mortality is measured using clinical report form at baseline, T1, T2, T3, T4, T5
2. Presence of a long-term complication post-SBE is measured using a symptoms survey at baseline, T1, T2, T3, T4, T5
3. Proportion of patients with serum sickness is measured using clinical report form at baseline, T1, T2, T3, T4, T5
4. Disability is measured using WHO Disability Assessment Schedule 2.0 at T3
5. Functionality is measured using Functional Independence Measure (FIM) at T3
6. Upper limbs strength is measured using handgrip strength at T3

7. Lower limbs strength is measured using 1-Minute Sit-to-Stand Test at T3
8. Quality of life is measured using EQ-5D at T3
9. Proportion of major bleeding is measured using clinical report form at T1
10. Proportion of non-major bleeding is measured using clinical report form at T1
11. Proportion of patients requiring debridement, skin grafting or amputation is measured using clinical report form at T1, T2
12. Total surface area of full thickness skin necrosis is measured using clinical report form at T1, T3

Completion date
31/07/2028

Eligibility

Key inclusion criteria
1. Be 18 years of age or older.
2. Be Brazilian.
3. Seek initial care at one of the healthcare units participating in the study.
4. Present signs of local or systemic complications.
5. Have the cognitive capacity to consent, assessed by the attending physician based on clinical history and physical examination.

Participant type(s)
Patient, Health professional, Other

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Be in critical condition or unable to communicate.

Date of first enrolment
01/06/2025

Date of final enrolment
02/02/2028

Locations

Countries of recruitment
Brazil

Study participating centre
Fundação de Medicina Tropical Dr. Heitor Vieira Dourado - FMT-HVD
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69040-000

Sponsor information

Organisation
Fundação de Medicina Tropical Doutor Heitor Vieira Dourado

Organisation
Liverpool School of Tropical Medicine

ROR
https://ror.org/03svjbs84

Organisation
Duke University

ROR
https://ror.org/00py81415

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository and will be included in the subsequent results publication. See outputs table for additional file of information.

IPD sharing plan summary
Stored in non-publicly available repository, Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files	Data collection and storage		02/04/2025	No	No
Statistical Analysis Plan			02/04/2025	No	No