Comprehensive clinical and laboratory assessment of visceral leishmaniasis (VL) patients

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BACKGROUND

- **Ethiopia** has the **second highest burden** of VL disease among Sub-Saharan African countries.
- Many studies, including clinical trials, focus on a selected patient population or marker
- **Poor treatment outcomes** for VL have become a challenging public health problem.
- **Relapse** is increasingly recognized as an important clinical challenge, with 10-15% estimated to develop relapse in the Ethiopian setting.

OBJECTIVES

GENERAL OBJECTIVE

To **systematically** describe clinical symptoms, investigations, laboratory tests and outcomes amongst VL patients

SPECIFIC OBJECTIVES

- To analyze treatment outcomes (**relapse**, **treatment failure** and **death)**
- To determine **how many VL patients have tuberculosis (**based on chest Xray, GeneXpert, ultrasound, and TB-LAM)
- To describe **blood culture results**
- To describe **antibiotic prescription patterns** and whether the CRP and other investigations support antibiotic prescription
- To describe **electrolyte and INR disturbances** before and during treatment

METHODS

- **Prospective** cohort study in *Leishmania* Research and Treatment Center (**LRTC**), University of Gondar Hospital. An average of 300 to 400 patients treated for VL annually.
- Study participants (≥12 years) with **clinically or parasitologically confirmed VL** with be recruited.
- Total estimated study recruitment period will be around two years.
- Patients are followed closely **during treatment and follow-up visits until 12 months after end of treatment for checking late relapse**.
- Status: recruitment started in FEB 2023. Currently, around **200 patients are enrolled**, and data entry is ongoing.

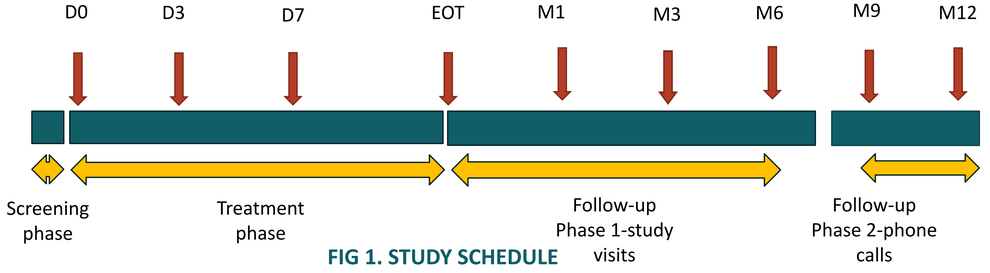


FIG 1. STUDY SCHEDULE

PRELIMINARY RESULTS FOR 52 PATIENTS

- 44/52 patients had primary VL, 8 patients had relapse VL
- 12/52 patients were coinfected with HIV
- 6/52 patients had a TB coinfection, of which 2 were diagnosed during VL treatment
- Ingesting/inhaling traditional medication was common (21/52). Many such patients had hepatotoxicity with elevated transaminases, INR, and signs of liver failure (**Fig 2)**
- SSG/PM was most commonly given, 8 patients were started on AmBisome, 12 HIV patients received AmBisome/Miltefosine

FIG 2. VL Patient who died due to liver failure having ingested traditional treatment

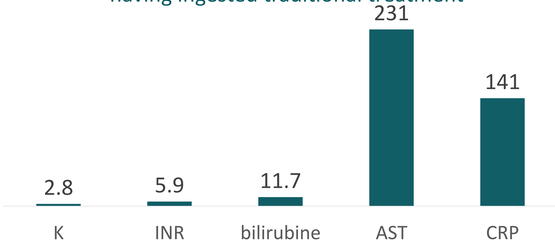
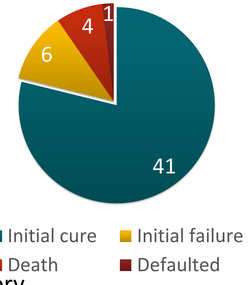


FIG 3. EoT Treatment outcomes



- Antibiotics were frequently given (39/52), and were mostly from the Watch category
- Median CRP results at baseline were 32 (range 2-190)
- 25/52 patients had hypokalemia at D0
- 3 patients developed PKDL during follow-up

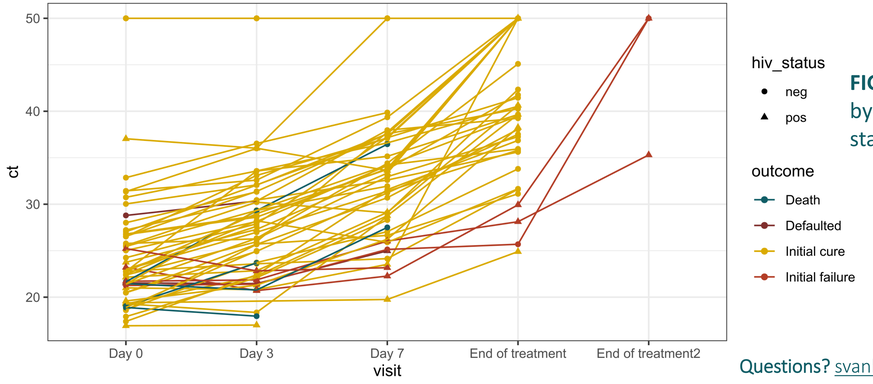


FIG 4. PCR Results shown in Ct-values by end of treatment outcome and HIV status.

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