

Overview of VL activities in Sudan

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Introduction

- VL is a priority (Gedarif: 2000).
- Descriptive research 1940s (Prof Satti and Prof Dawod)
- The Era of Professor EL-Hassan and Co-worker basic research from 1970- to date.
- Wealth of data on the epidemiology, immunopathology, Clinical Medicine, Entomology.
- paved the way for vaccines studies (Khalil, Musa, Brima).
- Since 2004 which have been conducting drug development trial under the auspices and LEAP (Financial and scientific unlimited support).

Where are we now?

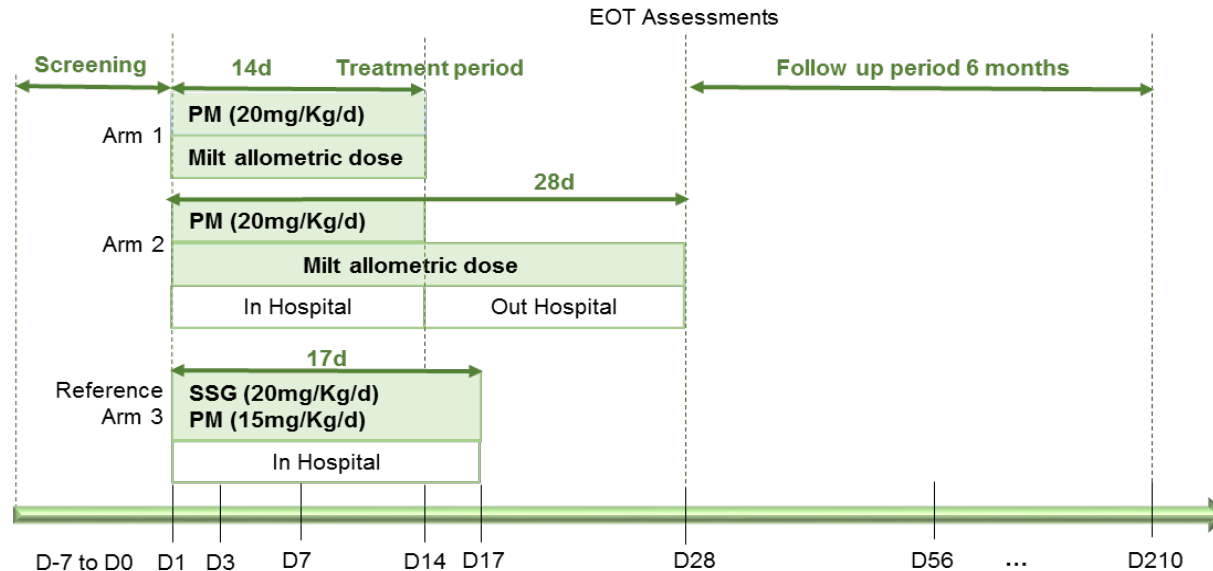
Phase III MF/PM clinical trial:

An Open Label, Phase III, Randomized Controlled, Multicentre Non-Inferiority Trial to Compare Efficacy and Safety of Miltefosine and Paromomycin with SSG and PM Combination for Treatment of Primary Visceral Leishmaniasis (VL) Patients in Eastern Africa

Secondary objectives: safety, PK, PD, compliance to oral treatment in outpatient settings

Patient population: confirmed primary VL patients 4-50y old, HIV neg, signed ICF

- Sudan: Dooka active; Tabarallak: SIV conducted; Umelkheir: in 6 wks time



MF/PM Phase III trial - Current status

Site	Dooka
# Screened	166
# VL positive	59
# enrolled	19
% enrolment	32%

Reason for screen failure	Dooka
3 - Age less than 4 years or more than 50 years	0%
4 - Declined consent	2%
5 - Female is pregnant, lactating, or refused contraception	0%
6 - Severely malnourished	18%
7 - Patient cannot comply with scheduled visits and procedures	6%
8 - VL relapse case	2%
9 - HIV positive	2%
10 - Lab abnormalities	24%
11 - Patient with clinical signs of severe VL disease	10%
12 - Patient with para kalazar dermal Leishmaniasis	0%
13 - Patient with history of treatment for Kalazar in last 6 months	0%
14 - Concomittant severe infection or chronic underlying disease	4%
15 - Abnormal ECG	0%
16 - Pre-existing hearing loss based on Audiometry	2%
17 - Others	0%

DNDi-MILT COMB-II-PKDL Trial: Current status

- Started in May 2018.
- Cases screened were 24.
- Enrolled were 15.
- 7 patients completed 3 months follow up.
- No SAEs.

Current status on active studies

- Slow recruitment in both studies:
 - 1) Bad roads because of the rains.
 - 2) Farming and grazing from June-September.
 - 3) Low numbers of VL patients during this time of the year.

Other research activities on VL in Sudan

- Small scale studies based at the Institute of Endemic Diseases namely purification of some parasite peptides for future vaccine studies.
- Virulence factors identification.
- Mapping of new foci and known foci for VL in Sudan.
- Xenodiagnosis study in Gedarif University.
- Evolution of the immune responses in PKDL over time.
- Animal reservoir for leishmania parasites.

Status on drug registration and VL treatment guidelines

- SSG and PM are registered in Sudan. This combination is the first line treatment.
- VL treatment guidelines was updated in 2016 and printed in 2017.
- Other drugs are in the essential list.
- There is always room for using some drugs on compassionate basis.

Challenges and Opportunities

- **Challenges:**

- Power supply, rains, fuel and roads.

- **Opportunities:**

- Government commitment.

- Community awareness.

- New sites. Tabarakallah site will start soon and Umelkheir will follow in 6 weeks time.

- Manpower especially clinicians and laboratory technologists.

Other activities/research the PIs are involved in

- The PIs in Sudan are involved in immuno-chemotherapy and prevention of PKDL.
- Conducting small scale studies in infectious diseases mainly leishmaniasis, tuberculosis and hepatitis.
- Supervision of MSc and PhD students by research.



Thanks for your attention