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 develop 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; Umekheir: in 6 wks time
## MF/PM Phase III trial - Current status

<table>
<thead>
<tr>
<th>Site</th>
<th>Dooka</th>
</tr>
</thead>
<tbody>
<tr>
<td># Screened</td>
<td>166</td>
</tr>
<tr>
<td># VL positive</td>
<td>59</td>
</tr>
<tr>
<td># enrolled</td>
<td>19</td>
</tr>
<tr>
<td>% enrolment</td>
<td>32%</td>
</tr>
</tbody>
</table>

### Reason for screen failure

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