PKDL IN SUDAN

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PKDL in Sudan

• Post-kala-azar dermal leishmaniasis (PKDL) is a complication of visceral leishmaniasis (VL)

• PKDL has also been reported in patients without a history of VL.

• It is prevalent in areas where L D is the causative organism for VL.
PKDL in Sudan

The highest incidence of PKDL has been reported from Sudan and Southern Sudan (AM Elhassan & EE Zijlestra, 2001)

In other VL endemic countries in East Africa PKDL is less common for reasons not well understood.

In Sudan most PKDL patients (85%) self heal within 6 months.
PKDL in Sudan

- Children are the most affected (a mean age of 6 years)
- Boys and girls are equally affected
- The interval between VL and PKDL development is 0 – 12 months.
- Only severe, complicated or chronic cases (≥ 6 months) are treated
PKDL Rate With different VL treatment Regimens

• Before 2010 SSG mono-therapy was the only available treatment in the regions

• Early studies in Sudan:

<table>
<thead>
<tr>
<th></th>
<th>VL treatment regimen</th>
<th>No. of VL Pts</th>
<th>VL cure rate</th>
<th>Year</th>
<th>PKDL rate</th>
<th>F U period</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sudan</td>
<td>irreg/inadeq dose SSG</td>
<td>131</td>
<td>na</td>
<td>1994</td>
<td>69%</td>
<td>na</td>
<td>Zijlstra 2000</td>
</tr>
<tr>
<td>Sudan</td>
<td>SSG 20 mg/kg x 15 days</td>
<td>65</td>
<td>63/65</td>
<td>1991-1993</td>
<td>35%</td>
<td>1-5 ys</td>
<td>Zijlstra 2000</td>
</tr>
</tbody>
</table>
### PKDL Rate With different VL treatment Regimens

- **PM/SSG combination studies:**

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<th>VL cure rate</th>
<th>PKDL rate</th>
<th>FU period</th>
<th>Ref.</th>
</tr>
</thead>
<tbody>
<tr>
<td>East Africa</td>
<td>SSG 20 mg/kg + PM 15 mg/kg x 17 days</td>
<td>381</td>
<td>91.4%</td>
<td>6%</td>
<td>6 months</td>
<td>Musa 2012</td>
</tr>
<tr>
<td></td>
<td>SSG 20 mg/kg x 30 days</td>
<td>386</td>
<td>93.9%</td>
<td>12%</td>
<td>6 months</td>
<td></td>
</tr>
<tr>
<td></td>
<td>PM 20 mg/kg x 21 days</td>
<td>205</td>
<td>84.3%</td>
<td>9%</td>
<td>6 months</td>
<td></td>
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</tbody>
</table>
Treatment of PKDL in Sudan

First line treatment
SSG at a dose of 20 mg/kg/day for 40–60 days

The second line treatment
AmBisome infusion at a dose of 2.5 mg/kg/day for 20 days
Treatment of PKDL in Sudan

- Current treatment options are not satisfactory.
- Carries high risk life threatening toxicities.
- Have long duration

- There is a need for safe, efficacious and easily administered regimen for PKDL.
On going Clinical Trial

Short course Regimens for Treatment of PKDL (Sudan)
<table>
<thead>
<tr>
<th>Protocol Title</th>
<th>An Open label, Randomized, Parallel arm Clinical Trial of Two Regimens to Assess the Safety and Efficacy for Treatment of Post Kala-azar Dermal Leishmaniasis (PKDL) Patients in Sudan</th>
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</thead>
<tbody>
<tr>
<td>Phase</td>
<td>Phase II</td>
</tr>
<tr>
<td>Site</td>
<td>Elhassan Centre for Tropical Medicine</td>
</tr>
</tbody>
</table>
Rationale and Objectives

- This will be the first large study in Eastern Africa for PKDL.
- This study aims to improve current treatment options.
- Another possible advantage is prevention of resistance.
Figure 1 - Overall study design

Screening | Treatment period | Follow-up period
---|---|---
D1 | D3 | D7 | D14 | D28 | D42 | 3 mo | 6 mo | 12 mo

Arm 1
- PM + MF
- MF

Arm 2
- AB + MF
- MF

SAE | Safety monitoring (AEs and SAEs)
The Trial Status

• The Study Started in May 2018
• 24 patients were screened
• 15 patients were enrolled
• 7 patients completed 3 months FU
• No SAE was reported
Challenges

Low recruitment due to:

➢ Heavy rains ➔ difficult transport.
➢ People were busy with their farms.

❖ Catch-up in the communing few months.
Thank You