

# 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

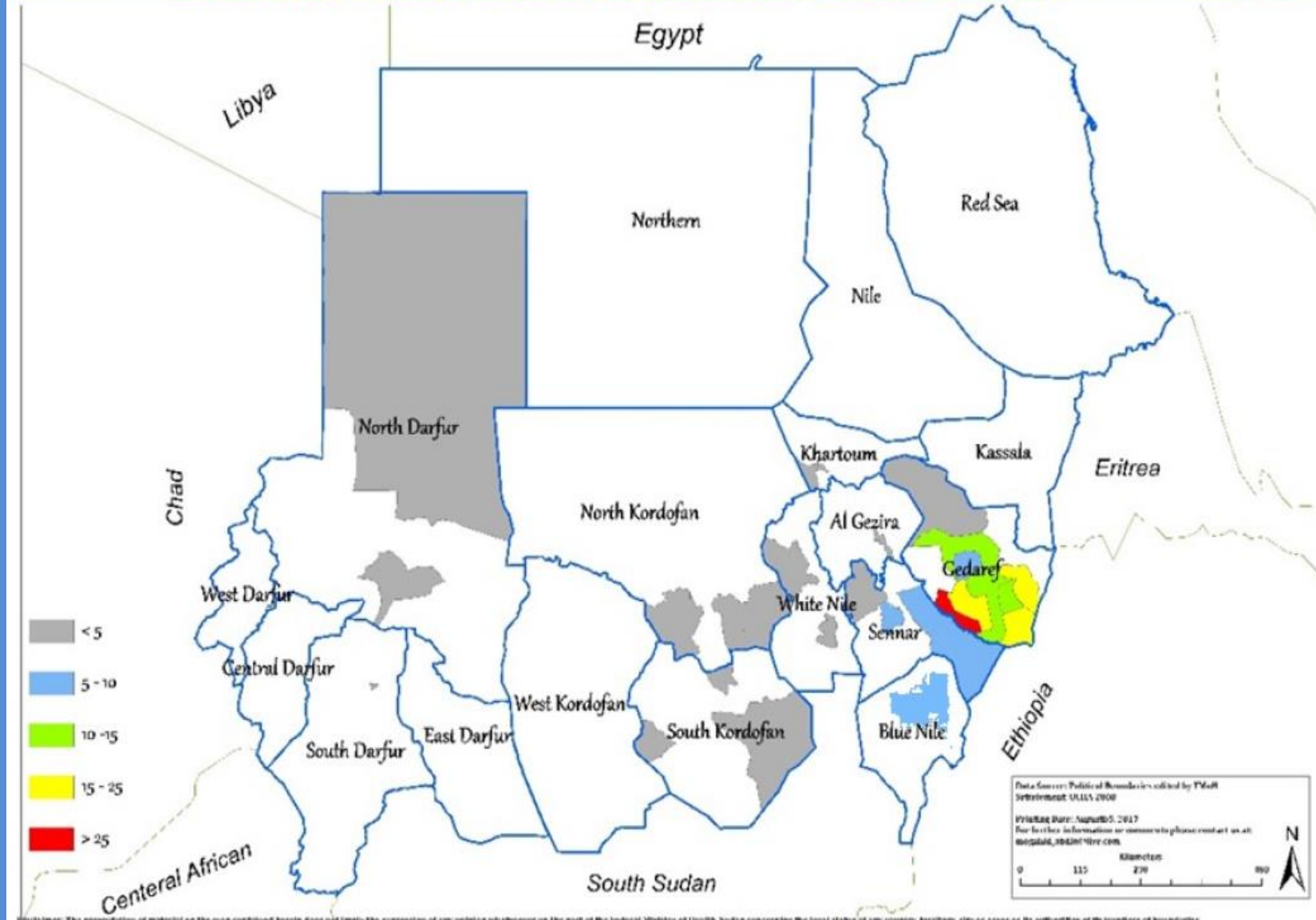
The highest incidence of PKDL has been reported from Sudan and Southern Sudan (AM Elhassan & EE Zijlestra,2001)

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.

# FMoH Incidence of Visceral leishmaniasis in Sudan

Public Health Information  
Map Ref NO 2017-01



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# 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 ( $\geq 6$  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:**

	VL treatment regimen	No. of VL Pts	VL cure rate	Year	PKDL rate	F U period	Reference
<b>Sudan</b>	<b>irreg/inadeq dose SSG</b>	<b>131</b>	<b>na</b>	<b>1994</b>	<b>69%</b>	<b>na</b>	<b>Zijlstra 2000</b>
<b>Sudan</b>	<b>SSG 20 mg/kg x 15 days</b>	<b>65</b>	<b>63/65</b>	<b>1991-1993</b>	<b>35%</b>	<b>1-5 ys</b>	<b>Zijlstra 2000</b>

# PKDL Rate With different VL treatment Regimens

- **PM/SSG combination studies:**

	VL treatment regimen	No. of VL Pts	VL cure rate	PKDL rate	FU period	Ref.
East Africa	SSG 20 mg/kg + PM 15 mg/kg x 17 days	381	91.4%	6%	6 months	Musa 2012
	SSG 20 mg/kg x 30 days	386	93.9%	12%	6 months	
	PM 20 mg/kg x 21 days	205	84.3%	9%	6 months	

# *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.

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On going Clinical Trial

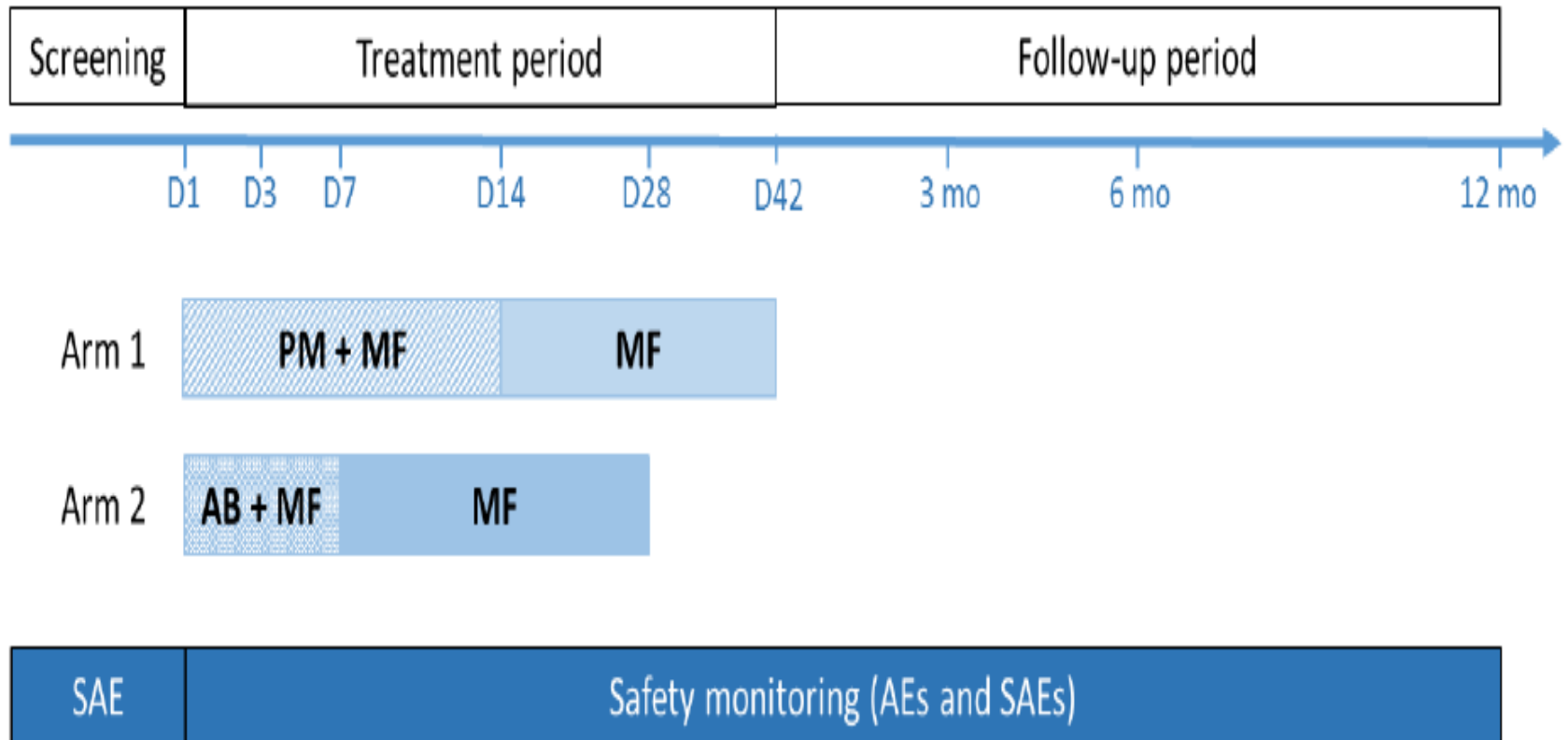
Short course Regimens for Treatment of PKDL  
(Sudan)

Protocol Title	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
Phase	Phase II
Site	Elhassan Centre for Tropical Medicine

# 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**



# 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.

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Thank You