A Pilot Study of Kaposi Sarcoma-Associated Herpes virus (KSHV) Gene Expression in Patients With Newly Diagnosed Kaposi Sarcoma (KS) in Malawi

Date: (day/month/year) ___/___/_____ consent signed

Eligibility Checklist

Inclusion Criteria (All must be Yes)	**Yes**	**NO**
Age >=18 years		
Clinically Diagnosed KS of the skin, lymph node (palpable disease), or oral cavity with at least 5 measurable lesions and 2 of the lesion equal to 5mm x 5mm		
HIV positive		
Ability and willingness to give informed consent		
Patients must, in the opinion of the Investigator, be capable of complying with the protocol		
ART naive		
Exclusion Criteria (All must be NO)	**Yes**	**NO**
Is the patient Pregnancy		
Breastfeeding		
Concurrent neoplasia requiring cytotoxic therapy		
Anti-neoplastic treatment for KS (including chemotherapy, radiation therapy, local therapy, biological therapy, or investigational therapy) within 4 weeks (6 weeks for nitrosourea or mitomycin-C) of study entry.		
Previous local therapy of any KS-indicator lesion within 60 days unless the lesion has clearly progressed since treatment.		
Is the Patient Eligible for the study?		

Study Form

Demographics

1. Study Number:_____

2. Age: ____ Years

3. DOB (if known) (day/month/year) _____/_____ /_____ ☐ Unknown birth date

4. Sex: M F

5. If female, is patient pregnant or breast feeding? Yes_____ No_____

History

6. When was the lesion/s first noticed by patient? months/years ago?

Months_____ Years_____

7. Is the patient being treated or has been treated for KS Yes_____ No_____

8. Is patient aware of their HIV status? Yes_____ No_____

9. If Yes, is patient on treatment for HIV? Yes_____ No_____

10. If Yes, type of treatment----------

11. How long has the patient been on this treatment? Months/years ago?

Months_____ Years_____

12A. WHO staging criteria

WHO Staging criteria. (Tick ☒ **all** that apply)**Stage 1**

Asymptomatic ❑

Stage 2

Loss of weight < 10%	
Minor mucocutaneous manifestations	
Herpes zoster	
Recurrent URTI	

Stage 3

In bed < 50% of normal daytime due to sickness	
Loss of weight > 10 %	
Chronic diarrhea > 1 month	
Constant or intermittent fever > 1 month	
Oral candidiasis	
Vulvovaginal candidiasis > 1 month	
Pulmonary tuberculosis	
Severe bacterial pneumonia	
Other severe bacterial infections (Myositis...)	
Oral hairy Leukoplakia	

Stage 4

In bed > 50% of normal daytime due to sickness	
Wasting syndrome	
Cryptococcosis extrapulmonary	
Pneumocystis carinii pneumonia	
Toxoplasmosis of the brain	
Encephalopathy, dementia...	
Candidiasis of the esophagus, trachea…	
Extrapulmonary tuberculosis	
Herpes simplex mucocutaneous >1m or visceral	
Kaposi	
Cytomegalovirus other than liver lymph mode	

WHO Clinical Stage:

❑ Stage 1 ❑ Stage 2 ❑ Stage 3 ❑ Stage 4

12B.

Symptoms			
a	Fever?	NO	YES
b	.Night Sweats	NO	YES
c	Headache?	NO	YES
d	Thrush?	NO	YES
e	Abdominal pain?	NO	YES
f	Vomiting?	NO	YES
g	Diarrhea? (> 3 motions per day)	NO	YES
h	Rash	NO	YES
I	Pain or numbness in your legs?	NO	YES
J	Cough?	NO	YES
k	Chest Pain	NO	YES
l	Yellow eyes	NO	YES
m	Vaginal Discharge	NO	YES
n	Genital Ulcers	NO	YES
o	Oedema	NO	YES
p	Weight loss	NO	YES
q	Any other new symptoms?	NO	YES

13. Current Medications: ----------

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14. Drug Allergies:
Allergy to lidocaine or prilocaine: Yes_____ No_____

Other----------

Physical Exam

15. Vital signs

Weight (kg)	Height (cm)	Temp (C)	BP mmhg	Pulse	Resp	Karnovsky

16. Number of cutaneous lesions (use code below) ----------
1=0, 2=≤10, 3=>10,≤50 4>50
If ≤ 10 lesions enter the number of lesions----------

17. Distribution of cutaneous KS. Answer each item.

	Presence	Presence
Site	Yes (1)	No(0)
Head		
Oral cavity		
Neck		
Chest		
Abdomen		
Back		
Right arm		
Left arm		
Right leg		
Left leg		
Right hand		
Left hand		
Right foot		
Left foot		
Genital		

18 . Size of 5 largest skin lesion (If more than 5 lesions otherwise record all lesions)
cm---------- Location_____

cm---------- Location_____

cm---------- Location_____

cm---------- Location_____

cm---------- Location_____

19. Location of the largest lesion----------

20. Is there lymph node involvement clinically? Yes_____ No_____

21. If yes, site involved----------

ACTG KS staging

	(Any of the following) "0"	**(Any of the following) "1"**
Tumor (T)	Confined to skin and/or lymph nodes and/or minimal oral disease [Note: Minimal oral disease is non-nodular KS confined to the palate.]	Tumor-associated edema or ulceration
		Extensive oral KS
		Gastrointestinal KS
		KS in other non-nodal viscera
Immune system (I)	CD4 cells ≥ = 200/microL	CD4 cells <200 per cubic millimeter
Systemic illness (S)	No history of OIs or thrush [Note: OIs are opportunistic infections.]	History of OIs and/or thrush
	No "B" symptoms [Note: "B" symptoms are unexplained fever, night sweats, >10% involuntary weight loss, or diarrhea persisting >2 weeks.]	"B" symptoms present
	Performance status ≥70 (Karnofsky)	Performance status <70
		Other HIV-related illness (e.g., neurological disease or lymphoma)

Record "0" or "1" according to presence of items in the appropriate column from above.

Resulting ACTG KS staging score: ___T_____I_____S_____

Laboratory Evaluation and Information

22. Blood collected into one 10 ml EDTA bottle collected. Yes_____

23. One punch biopsy collected. Yes_____

24. HIV status confirmed positive Yes_____

Note: The following items will be entered when available from the lab

25. CD4 count: _____

26. HIV viral load_____

27. KSHV viral load in PBMC _____

28. KSHV viral load in plasma_____

29. KSHV antibody levels _____

30. KSHV/HHV-8 Thymidine kinase (Orf24) gene expression in tissue_____

31. KSHV/HHV-8 Phosphorylase (orf36) gene expression in tissue _____