Participant flow diagram

Excluded if NOT ART naïve or renal histology other than HIVAN

354 HIV positive renal biopsies

40 ART naïve patients with HIVAN on renal biopsy

2 excluded: 1 with Kaposi's sarcoma and 1 moved provinces 1 week after randomisation

Concealment Randomisation

21 Assigned to ART + corticosteroids [ART + C]

17 assigned to ART alone

21 analysed for primary outcome

17 analysed for primary outcome

7 demised

3 lost to follow up & 1 demised

12 Consented to repeat biopsy

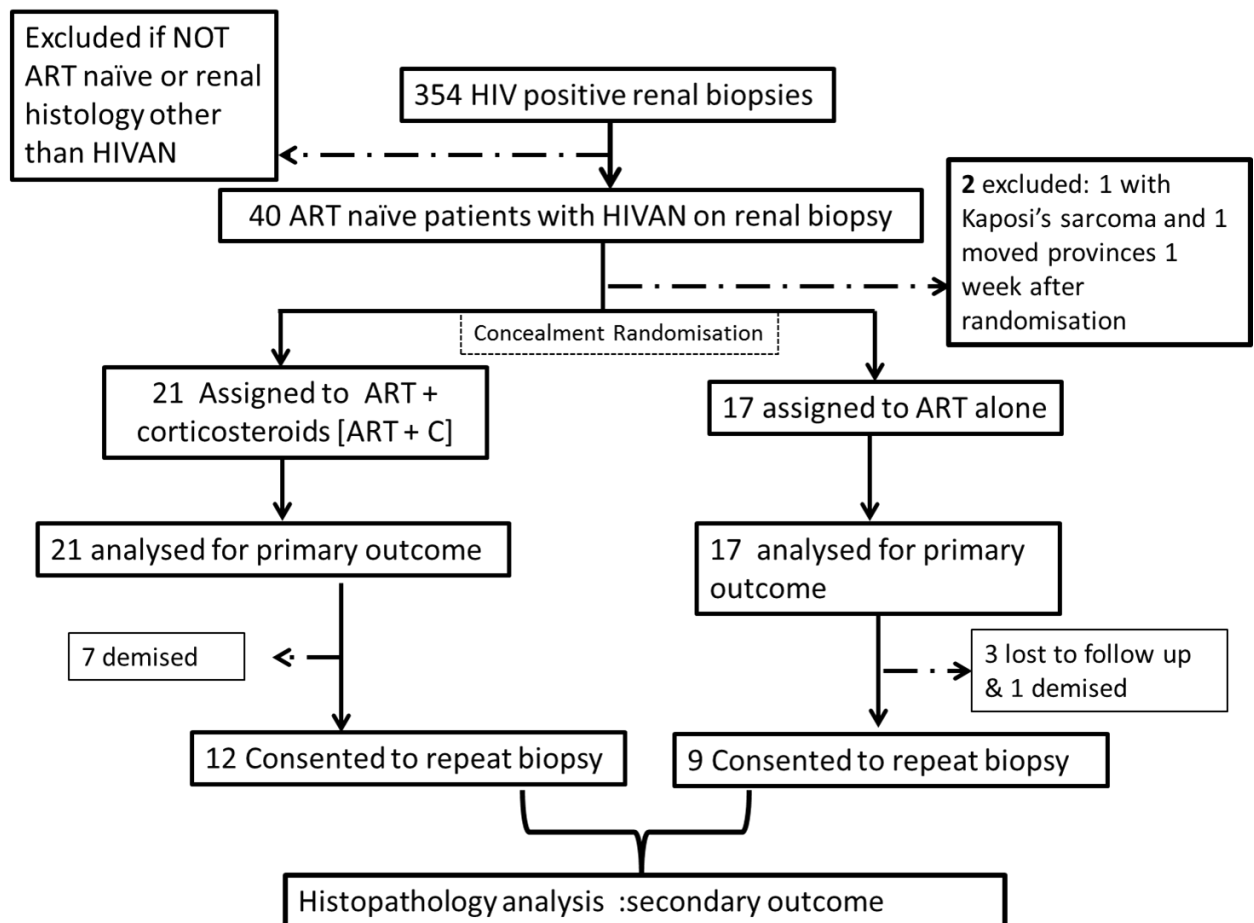9 Consented to repeat biopsy

Histopathology analysis : secondary outcome

Baseline characteristics

Baseline demographic, clinical and biochemical parameters.

	ALL N= 38	[ART+C] N= 21	[ART Alone] N= 17	P Value*
Demographics				
Gender (female), n[%]	25 [65.8%]	14 [66%]	11 [64%]	0.584[a]
Age (years) median IQR	34.5 [27-40]	38 [27-47]	29 [26-38]	0.112[b]
Clinical parameters				
Systolic BP (mmHg) median [IQR]	118 [110-121]	118 [110-120]	120 [110-121]	0.478[b]
Diastolic BP (mmHg median [IQR]	73.5 [64-80]	70 [58-80]	76 [70-80]	0.085[b]
Diabetes; n [%}	1 [2.6%]	1 [4.8%]	0	1.000[a]
Hypertension, n [%}	7 [18.4%]	5 [23.8%]	2 [11.8%]	0.306[a]
Tuberculosis at baseline, n [%}	10 [26.3]	7 [33.3%]	3 [17.6%]	0.242[a]
Commenced on ACE/ARB; n [%}	27 [71.1%]	14 [66.7%]	12 [70.6%]	0.519[a]
ART regimen at baseline, n [%}				0.332[a]
- D4T/3TC/EFV or NEV	20 [52.6%]	11 [52.4%]	9 [52.9%]	
- ABC/3TC/EFVor NEV	9 [23.7%]	7 [33.3%]	2 [11.8%]	
- ZVD/3TC/EFV or NEV	6 [15.8%]	2 [9.5%]	4 [23.5%]	
- Other/unknown	3 [7.9%]	1 [4.8%]	2 [11.8%]	
Biochemical parameters				
eGFR (ml/min/1.73m^2) median[IQR] eGFR (ml/min/1.73m^2) mean [SD]	43.5 [26-70]	35 [18 – 46] 38[25.9]	47 [39 – 97] 65[34.7]	0.017[b]
CD4 (cells/mm^3) median[IQR]	158 [63-309]	158 [36-272]	173 [104-352]	0.437[b]
HIV VL (Log 10) (cps/ml)	4.77 [3.87-5.29]	4.77 [4.5-5.29]	4.69 [2.75-5.3]	0.5623[b]
Albumin (g/L)	30 [25-33]	29 [24-32]	30.5 [27-36]	0.262[b]
uPCR (g/mmol)	0.35 [0.14-0.54]	0.38 [0.17-0.52]	0.23 [0.13-0.59]	0.427[b]
Haemoglobin (g/dL)	8.4 [7.2-9.7]	8.5 [7.7-9.4]	8 [7.1-10.2]	0.607[b]
Cholesterol(mmol/l)	4.4 [3.4- 5.4]	4.4 [3.3-5.1]	4.55 [3.5-5.8]	0.624[b]

Note: [ART + C] = Antiretrovirals + corticosteroids; [ART Alone] = Antiretrovirals alone; IQR= interquartile range ;BP = Blood pressure; ACEi= angiotensin converting enzyme inhibitor; ARB= angiotensin receptor blocker; D4T - Stavudine; 3TC - Lamivudine; NEV - Nevirapine; ABC – Abacavir; EFV – Efavirenz; ZVD – Zidovudine; uPCR – urine protein-to-creatinine ratio, HIV VL – HIV viral load; eGFR – estimated glomerular filtration rate; SD = standard deviation.
a= Fishers Exact test, b= Wilcoxon Rank-Sum test
* p-value comparison of [ART+C] vs [ART Alone]

Primary outcome

	[ART + Corticosteroids]				[ART Alone]			
Study No.	Baseline eGFR	Last follow up eGFR	Comment	Study No.	Baseline eGFR	Last follow up eGFR	Comment
1	22	51	Died: last eGFR =7 months	22	44	60	Last eGFR =16 months[LtFup]
2	116	125	Full dataset	23	70	57	Full dataset
3	32	58	Full dataset	24	91.5	140	Full dataset
4	51	64	Full dataset	25	111	120	Full data set
5	86	123	Full dataset	26	29	15	Died at 1 month
6	12	72	Full dataset	27	39	26	Last eGFR=14 month[LTFup]
7	18	113	Full dataset	28	127	147	last eGFR =14 month[LTFup]
8	18	38	Full dataset	29	26	55	Full data set
9	35	99	Full dataset	30	46	71	Full data set
10	44	113	Full dataset	31	102	111	Full data set
11	46	47	Full dataset	32	43	51	Full data set
12	63	105	Full dataset	33	47	71	Full dataset
13	17	38	Died: last eGFR=7 months	34	14	24	Full dataset
14	35	57	Died: last eGFR=7 months	35	35	35	Full dataset
15	15	16	Died: last eGFR=1 month	36	101	90	Full data set
16	32	63	Full data set	37	97	103	Last eGFR = 2 months[LTFup]
17	14	134	Full dataset	38	83	89	Full data set
18	46	69	Full dataset				
19	15	17.4	Last eGFR=19months[LTFup]				
20	35	49	Died: last eGFR 20 months				
21	46	61	Died last eGFR 19 months				

The change [Δ] in clinical and biochemical parameters over 24 months.

Median change [Δ] in parameters at 24 months [IQR]	[ART + C]	[ART Alone]	P Value[a]
Biochemical parameters			
Change in eGFR (ml/min/1.73m^2) [IQR]	23 [14-42]	9 [0-20]	0.006
Change in uPCR (gm/mmol) [IQR]	-0.12 [-0.32; 0.08]	-0.12 [-0.55; 0.06]	0.691

Note: [ART + C] = Antiretrovirals + corticosteroids ; [ART Alone] = Antiretrovirals alone, a = Wilcoxon Rank-Sum test

Secondary outcomes

Improvement in histological feature

Histological feature	ART + C N=12 Repeat biopsy (%)	ART alone N=9 Repeat biopsy (%)	P Value[a]
Lymphocytic infiltration	50.0%	55.6%	1.000
Plasma cell infiltration	75%	44.4%	0.203
Interstitial fibrosis	75.0%	44.4%	0.203
Microcysts	41.8%	22.2%	0.642
Parietal cell hypertrophy or hyperplasia	50.0%	22.2%	0.367
Podocyte hypertrophy or hyperplasia	16.67%	22.2%	1.000

Note: [ART + C] = Antiretrovirals + corticosteroids ; [ART Alone] = Antiretrovirals alone

a= Fisher's Exact Test to compare repeat histology between groups

➔ The other secondary outcome were adverse events described below

Adverse events:

	Number of participants	Details	Time frame	Other
Morbidity : all in the group receiving corticosteroids	2	Herpes Zoster	10-14 days after corticosteroids	Successful treatment
Mortality	8	1		
No corticosteroid group	1		Occurred within 1 month of starting antiretroviral therapy	From Tuberculosis
Corticosteroid group	7 total	1 patient 3 patients 3 patients	1 month from start of trial First 7 months After completing steroids	Unknown cause Overwhelming sepsis Overwhelming sepsis - 1 had tuberculosis