



TasP

Antiretroviral Treatment as Prevention - ANRS 12249
(Ukuphila kwami, ukuphila kwethu)

1 of 2

Ukuphila kwami, ukuphila kwethu

Africa Centre TasP Trial

SAE-41

ANRS 12249

Serious Adverse Event Reporting

ANRS 12249 Initial SAE Notification

Completed forms must be sent to
ANRS within 48 hrs.
Email: pharmacovigilance@anrs.fr
Fax: +33 153 946 002



00026538

SAE No. _____ SAE Visit Date 20130318
Initial Notification Date 20130319 Notification time 1605

1. Patient details

TasP ID 11621
Name MBAKENI ASSALOM BUTHELEZI
Sex ☒ Male ☐ Female
Date of birth 19311216
Enrolment date 20120327

2. Measurements

Height 160 Cms
Last known: Weight 54.90 Kgs Weight Date 20130227
CD4 count 160 CD4 Date 20130306
Viral Load 3.02 Viral Load Date 20130227

3. By which criteria is this adverse event considered to be "Serious"?

Tick all that apply

- ☐ Resulted in death → Date of death _____ Probable cause _____
☐ Life threatening (i.e. at risk of death at time of event)
☒ Caused or prolonged hospitalisation (not elective hospitalisation for a pre-existing condition)
☐ Persistent or significant disability / incapacity
☐ Congenital abnormality / birth defect
☐ Grade 4 clinical and biological events
☐ Other serious, medically-important condition → Specify _____

4. Details of SAE

Enter each adverse event (e.g. symptom, sign, syndrome or diagnosis) on a separate line

Event Name	Date investigator became aware	Date of onset of SAE
WORSENING CHRONIC KIDNEY DISEASE	20130315	20130227
UNCONTROLLED HYPERTENSION	20130315	20130227
3.		
4.		
5.		

5. Description of SAE

Include details of body site, relevant laboratory tests, treatments received and relevant medical history.
Attach copies of any relevant hospital records, laboratory test results etc.

ADMITTED HLABISA HOSPITAL 2013/03/18 WITH POORLY CONTROLLED HYPERTENSION + WORSENING CHRONIC KIDNEY DISEASE. HYPERTENSION SINCE 2010 (ON 3 ANTIHYPERTENSIVE DRUGS). PRIOR TO ART, CREATININE 225 (2012/03/27) BUT IMPROVED TO 99 (2012/08/08). NOW FURTHER DETERIORATION TO 247 (2013/02/27) + 340 (2013/03/19, ON ADMISSION TO HOSPITAL). BP PERSISTENTLY ELEVATED > 160/80 DURING FOLLOW-UP.

6. Medications

List all drugs taken (or prescribed) before occurrence of SAE

Generic Name	Daily dose	Route of administration	Indication	Date started	Date stopped	Causality assessment	Expected reaction? (BNF/SPC)	Action taken
1. ZIDOVUDINE	300mg b.i.d	oral	HIV	20120412		X Unrelated	Yes	X None
						Poss. related	X No	Reduce
						Cannot be assessed		Interrupt Stop
2. LAMIVUDINE	150mg o.d	oral	HIV	20120412		X Unrelated	Yes	X None
						Poss. related	X No	Reduce
						Cannot be assessed		Interrupt Stop
3. EFAMVIZ	600mg o.d	oral	HIV	20120412		X Unrelated	Yes	X None
						Poss. related	X No	Reduce
						Cannot be assessed		Interrupt Stop
4. HYDROCHLOROTHIAZIDE	12.5mg o.d	oral	HYPERTENSION	20100101		Unrelated	X Yes	X None
						X Poss. related	No	Reduce
						Cannot be assessed		Inter Stop

7. Other causes of SAE, if unrelated to drugs mentioned in Section 6 above

7a. According to the physician, is this SAE likely to be related to participation in the research?

Yes ☐ No ☒

7b. According to the physician, is this SAE related to any causes other than the research?

This includes the patient's medical history

X Yes ☒ No ☐

Describe

LIKELY TO BE WORSENING CHRONIC KIDNEY DISEASE DUE TO HYPERTENSION BUT COULD ALSO BE HIV-ASSOCIATED NEPHROPATHY

8. SAE Outcome

Unknown to date

X Ongoing

Improved

Recovered

A complementary SAE notification must be submitted within 8 days

Date of recovery

Recovered without sequelae
or

Recovered with sequelae

Describe

Physician reporting SAE

Name RICHARD LESSELLS

Signature [Signature]

Date form completed 20130319