



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

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Africa Centre TasP Trial

Serious Adverse-Event Reporting

ANRS 12249 Initial SAE Notification

SAE-AI

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



00125371

SAE No.

SAE Visit Date

2014 08 25

Initial Notification Date

2014 08 26

Notification time

14 20

1. Patient details

TasP ID

32824

Name

J.K.M

Sex

Male

Female

Date of birth

1975 02 15

Enrolment date

2014 08 18

2. Measurements

Height

Cms

Last known: Weight

66 00

Kgs

Weight Date

2014 08 19

CD4 count

CD4 Date

Viral Load

Viral Load Date

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



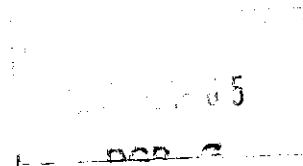
Congenital abnormality / birth defect



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

1. Grade 3 renal failure 2014 08 21 2014 08 19

2.

3.

4.

5.

5. Description of SAE

Include details of body site, relevant laboratory tests, treatments received and relevant medical history.

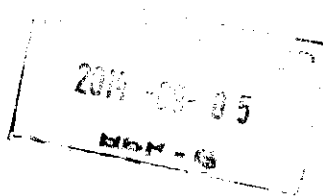
Attach copies of any relevant hospital records, laboratory test results etc.

The patient transferred to TasP from government clinic. She was already on ARV's TDF/3TC/EFV on 'atrogia' since July 2014. TasP baseline bloods found creatinine of 341, and urea 15.1. The results were seen 21/8/14. The patient only attended TasP clinic 26/8/14. She was ambulant but had experienced weakness. She was immediately referred from TasP Clinic to Hlabisa hospital for renal monitoring. TDF was stopped as this is the likely cause.

## 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. Tenofovir	300mg	P.O.	HIV	2014 07	2014 08 25	Unrelated	<input checked="" type="radio"/> Yes	None
						<input checked="" type="radio"/> Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								<input checked="" type="radio"/> Stop
2. lamivudine	300mg	P.O.	HIV	2014 07	2014 08 25	Unrelated	<input checked="" type="radio"/> Yes	None
						Poss. related	<input checked="" type="radio"/> No	Reduce
						Cannot be assessed		<input checked="" type="radio"/> Interrupt
								Stop
3. efavirenz	600mg	P.O.	HIV	2014 07	2014 08 25	Unrelated	<input checked="" type="radio"/> Yes	None
						Poss. related	<input checked="" type="radio"/> No	Reduce
						Cannot be assessed		<input checked="" type="radio"/> Interrupt
								Stop
4.						Unrelated	<input checked="" type="radio"/> Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								Stop
5.						Unrelated	<input checked="" type="radio"/> Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								Stop
6.						Unrelated	<input checked="" type="radio"/> Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								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

Yes ☒ No ☐  
Describe

likely due to taking tenofovir, which she commenced prior to enrolling at TasP.  
No previous renal past medical history.

## 8. SAE Outcome

Died

Unknown to date

☒ 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 MELANIE HILL

Signature

Date form completed 2014 08 26