



TasP

Antiretroviral Treatment as Prevention - ANRS 12249
(«*enrichir, soigner, protéger*» pour la santé)



00317458

Ukuphila kwami, ukuphila kwethu

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
Fax: +33 153 946 002

SAE No.

SAE Visit Date

20150328

Initial Notification Date

20150422

Notification time

1420

1. Patient details

TasP ID

22176

Name

T.M.

Sex

Male

☒ Female

Date of birth

19561009

Enrolment date

20130514

2. Measurements

Height

Cms

Last known: Weight

Kgs

Weight Date

CD4 count 818

CD4 Date

20150324

Viral Load <40

Viral Load Date

20150324

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

Tick all that apply

☐ Resulted in death → Date of death

☐ 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. Renal failure 20150327 20150324

2. Pneumonia 20150422 20150408

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.

Routine blood test on 24/3/15 showed renal failure, with creatinine 859. Patient was uncontactable initially. She finally attended Alcobisa hospital on 8/4/15. Alcobisa hospital missed her renal failure (creatinine on admission 625), but diagnosed her with pneumonia (raised WCC, consolidation seen on CXR). She was treated with IV antibiotics, but her atazanavir was continued during admission. She was discharged on 17/4/15. On TDF for 2 years prior to this as TDF unlikely cause. Probable renal failure 2° sepsis due to pneumonia.

6. Medications

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

	Generic Name	Daily dose	Route of administration	Indication	Date started	Causality assessment	Expected reaction? (BNF/SPC)	Action taken
					Date stopped			
1.	Atripla	1	PO	HIV	2013 10 09	Unrelated	<input checked="" type="radio"/> Yes	<input checked="" type="radio"/> None
						<input checked="" type="radio"/> Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								Stop
2.						Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								Stop
3.						Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								Stop
4.						Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								Stop
5.						Unrelated		None
						Poss. related	Yes	Reduce
						Cannot be assessed	No	Interrupt
								Stop
6.						Unrelated		None
						Poss. related	Yes	Reduce
						Cannot be assessed	No	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

This patient is immunocompromised + would have been at risk of pneumonia/sepsis regardless of participation in TASP

8. SAE Outcome

Died

Unknown to date

Ongoing

Improved

A complementary SAE notification must be submitted within 8 days

☒ Recovered

Date of recovery 2015 04 17

Recovered without sequelae

or

Recovered with sequelae

Describe

Unknown whether renal failure is ongoing as hospital did not re-check U&E. TASP will check U&E.

Physician reporting SAE

Name MELANIE HILL

Signature 

Date form completed 20150422