

**TasP**Antiretroviral Treatment as Prevention - ANRS 12249
(Ukuphila kwami, ukuphila kwethu: my health for our health)

00125381

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

20141016

Initial Notification Date

20141020

Notification time

1030

1. Patient details

TasP ID

48018

Name

W.T

Sex

Male

☒ Female

Date of birth

19570828

Enrolment date

20141002

2. Measurements

Height

155 cms

Last known: Weight

40.7

Kgs

CD4 count

540

Viral Load

<40

Weight Date

20141009

CD4 Date

20141002

Viral Load Date

20141002

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 NameDate investigator
became awareDate of onset of SAE

1. Renal failure 20141009 20101002

2. Chronic diarrhoea 20141009 20140926

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.

Participant newly enrolled in trial. CD4 540; Viral load suppressed on ZTC, TDF, EFV as odimmune. She is also hypertensive on treatment. Her baseline bloods showed urea 10.3 & creatinine 256. She was referred to hospital; all nephrotoxic drugs were stopped. She was admitted from 10/10/2014 & discharged 15/10/14 with very little clinical improvement. She is due for review in 2 weeks at the hospital.

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. Hydrochlorothiazide	12.5mg	oral	hypertension	20100101	20100101	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. Enalapril	10mg	oral	hypertension	20141001	20141002	Unrelated	<input checked="" type="radio"/> Yes	None
						<input checked="" type="radio"/> Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								<input checked="" type="radio"/> Stop
3. Amlodipine	5mg	oral	hypertension	20141001	20141002	<input checked="" type="radio"/> Unrelated	Yes	<input checked="" type="radio"/> None
						Poss. related	<input checked="" type="radio"/> No	Reduce
						Cannot be assessed		Interrupt
								Stop
4. Tenofovir	300mg	oral	HIV	20140520	20140520	Unrelated	<input checked="" type="radio"/> Yes	None
						<input checked="" type="radio"/> Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								<input checked="" type="radio"/> Stop
5. Emtricitabine	200mg	oral	HIV	20140520	20140520	<input checked="" type="radio"/> Unrelated	Yes	None
						Poss. related	<input checked="" type="radio"/> No	Reduce
						Cannot be assessed	<input checked="" type="radio"/> No	Interrupt
								Stop
6. Efavirenz	600mg	oral	HIV	20110725	20110725	<input checked="" type="radio"/> Unrelated	Yes	<input checked="" type="radio"/> None
						Poss. related	<input checked="" type="radio"/> 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

Participant had diarrhoea, admitted use of herbal medicines and had been using nephrotoxic medication.

8. SAE Outcome

Died

Unknown to date

Ongoing

Improved

→ A complementary SAE notification must be submitted within 8 days

☒ Recovered

→ Date of recovery

Recovered without sequelae

or

☒ Recovered with sequelae

Describe

Urea and creatinine still high, however diarrhoea has resolved.

Physician reporting SAE

Name DR GUGIELITTE MIKHULISI

Signature

Date form completed 20141020