



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
Fax: +33 153 946 002



00093266

SAE No.

SAE Visit Date

2013 08 20

Initial Notification Date

2013 08 22

Notification time

1. Patient details

TasP ID

24642

Name

S.G

Sex

☒ Male

☐ Female

Date of birth

1959 06 02

Enrolment date

2013 04 30

2. Measurements

Height

160 Cms

Last known: Weight

52

Kgs

Weight Date

2013 04 30

CD4 count

514

CD4 Date

2013 04 30

Viral Load

106100

Viral Load Date

2013 04 30

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

Tick all that apply

- ☒ Resulted in death → Date of death TO FOLLOW Probable cause PROBABLE RENAL FAILURE
- ☐ 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. DEATH

2013 08 20 2013 07 11

MORE INFORMATION
TO FOLLOW

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.

Patient failed to attend appointment on 4/7/2013, so was visited by a tracker. Tracker found him unwell, vomiting, dizziness, headache, fever, loss of appetite with weight loss. He was taken to the trial clinic and subsequently referred to the primary healthcare clinic on same day. He was treated and discharged. Informed by family he died 3 weeks ago. Still trying to ascertain date of death.

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. ATRIPLA	300/200/600	PO	HN	20130513		Unrelated	Yes	None
						<input checked="" type="radio"/> Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								Stop
2. HYDROCHLORID THIAZIDE	12.5MG	PO	HYPERTENSION	20130430		Unrelated	Yes	None
						<input checked="" type="radio"/> Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								Stop
3. ISONIAZID	300mg	PO	TB PROPHYLAXIS	20130606		<input checked="" type="radio"/> Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								Stop
4. VITAMIN B12	T	PO	SUPPLEMENT	20130513		<input checked="" type="radio"/> 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?

☒ Yes ☐ No

This includes the patient's medical history

Describe

PATIENT MUST HAVE SUFFERED FROM DEHYDRATION 2° TO VOMITING EXACERBATED BY TENOFOVIR + HYDROCHLOROTHIAZIDE.

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

COLEMAN /WUJ/

Signature

Xup

Date form completed

20130822