



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



00057404

*Nkandweni*  
**Ukuphila kwami, ukuphila kwethu**  
Africa Centre TasP Trial

SAE-AI

## Serious Adverse Event Reporting

### ANRS 12249 Initial SAE Notification

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

SAE No.

SAE Visit Date

2013 07 23

Initial Notification Date

2013 07 24

Notification time

#### 1. Patient details

TasP ID

11616

Name

E.B.

Sex



Male

Female

Date of birth

19611111

Enrolment date

20120403

DATA CAPTURED

2013 -07-25

DC QC

#### 2. Measurements

Height

165 Cms

Last known: Weight

69.2

Kgs

Weight Date

20130709

CD4 count

428

CD4 Date

20130319

Viral Load

< 50

Viral Load Date

20130319

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

Tick all that apply



Resulted in death → Date of death

2013 07 21

Probable cause

UNKNOWN



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

Date of onset of SAE

became aware

1.

DEATH,  
CAUSE UNKNOWN

2013 07 23

2013 07 21

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 was last seen in clinic on 09/07/2013. Complained of no symptoms and doing well on ART. Complained of a severe headache on 21/7/2013 and rushed to hospital. Died on arrival to hospital. He is a known hypertensive, last blood pressure was 132/51 mmHg. A haemorrhagic stroke could be a probable cause 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 TDF/FTC/EFV	300/200/600	PO	HIV	20120517		Unrelated Poss. related Cannot be assessed	Yes No	None Reduce Interrupt Stop
2. HYDROCHLOROTHIAZIDE	12.5mg	PO	HYPERTENSION	20110208		Unrelated Poss. related Cannot be assessed	Yes No	None Reduce Interrupt Stop
3. ENALAPRIL	10mg	PO	HYPERTENSION	20110404		Unrelated Poss. related Cannot be assessed	Yes No	None Reduce Interrupt Stop
4. AMLODIPINE	5mg	PO	HYPERTENSION	20130319		Unrelated Poss. related Cannot be assessed	Yes No	None Reduce Interrupt Stop
5. ASPIRIN	75mg	PO	SECONDARY PREVENTION	20110404		Unrelated Poss. related Cannot be assessed	Yes No	None Reduce Interrupt Stop
6. VIT B12	1	PO	SUPPLEMENT	20130516		Unrelated Poss. related Cannot be assessed	Yes No	None Reduce 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

PROBABLE HAEMORRHAGIC STROKE.

## 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

COLIN S. IHWUJI

Signature

*[Signature]*

Date form completed

20130724