



TasP

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

Ukuphila kwami, ukuphila kwethu

Africa Centre TasP Trial

Serious Adverse Event Reporting

SAE-AI

v31 Jan 2013



00093284

ANRS 12249 Initial SAE Notification

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

SAE No.	SAE Visit Date	20140121
	Initial Notification Date	20140123
	Notification time	

1. Patient details

TasP ID 25125
Name T.M.
Sex ☐ Male ☒ Female
Date of birth 19711114
Enrolment date 20130618

2. Measurements

Height 159 Cms
Last known: Weight 86.0 Kgs Weight Date 20131209
CD4 count 202 CD4 Date 20130618
Viral Load 142300 Viral Load Date 20131106

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

Tick all that apply

- ☒ Resulted in death → Date of death 20140103 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. Vomiting	20140122	20131209
2.	YY Y Y M M D D	YY Y Y M M D D
3.		
4.	YY Y Y M M D D	YY Y Y M M D D
5.		

DATA CAPTURE
2014-02-24
DCP-F

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 unwell and complained of severe vomiting. Details surrounding death unclear. Died while on a visit to different city outside of trial area. Defaulted on her ART when presented at baseline. She was restarted on her usual regimen of AZT/3TC/EFV.

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. ZIDOVUDINE	300MG	ORAL	HW	20120223		Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								Stop
2. LAMIVUDINE	300MG	ORAL	HW	20061123		Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								Stop
3. EFVIRENZ	600MG	ORAL	HW	20061123		Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								Stop
4. HYDROCHLOROTHIAZIDE	12.5MG	ORAL	HW	u u u u u u u		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 UNABLE TO COMMENT

8. SAE Outcome

☒ Died

Unknown to date
Ongoing
Improved
Recovered → Date of recovery

Recovered without sequelae
or
Recovered with sequelae
→ Describe

Physician reporting SAE

Name

Dr COLLINS / HWJ1

Signature

KMP

Date form completed

20140123