



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

KWASUMBE
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
Fax: +33 153 946 002



00057413

SAE No.

SAE Visit Date

20130521

Initial Notification Date

20130527

Notification time

1730

1. Patient details

TasP ID

28186

Name

M.M

Sex

Male

☒ Female

Date of birth

19601010

Enrolment date

20130521

2. Measurements

Height

113 cms

Last known: Weight

48.0

Kgs

Weight Date

20130521

CD4 count

340

CD4 Date

20130521

Viral Load

<50

Viral Load Date

20130521

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 Name

Date investigator
became aware

Date of onset of SAE

1. RAISED GGT 20130523 2013uuuu

2.

3.

4.

5.

DATA CAPTURE

2013-07-10

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.

Markedly raised gamma glutamyl-transferase - 515 u/L,
marginally raised alkaline phosphatase. History
suggests alcohol abuse.

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. TENOFORVIR	300mg	PO	HIV	20110609		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. LAMIVUDINE	300mg	PO	HIV	20080417		Unrelated	<input checked="" type="radio"/> Yes	<input checked="" type="radio"/> None
						<input checked="" type="radio"/> Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								Stop
3. EFVIRENZ	600mg	PO	HIV	20080417		Unrelated	<input checked="" type="radio"/> Yes	<input checked="" type="radio"/> None
						<input checked="" type="radio"/> 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

Probably alcohol abuse, although HAART can cause elevated γ -GT

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

COLLINS JHUTTI

Signature

Xinf

Date form completed

20130527