



TasP

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

Ukuphila kwami, ukuphila kwethu

Africa Centre TasP Trial

SAE-AI

031 Jan 2013

Serious Adverse Event Reporting



00093286

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

20140319

Initial Notification Date

20140327

Notification time

1. Patient details

TasP ID

26657

Name

D.M.

Sex

☒

Male

☐

Female

Date of birth

19690425

Enrolment date

20130819

DATA CAPTURED
2014-03-27
DC AC

2. Measurements

Height

160 Cms

Last known: Weight

60 Kgs

Kgs

Weight Date

20140319

CD4 count

528

CD4 Date

20130819

Viral Load

<50

Viral Load Date

20140123

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 GAMMA 20140324 20140319
GLUTAMYL TRANSFERASE

2. Y Y Y Y M M D D Y Y Y Y M M D D

3. Y Y Y Y M M D D Y Y Y Y M M D D

4. Y Y Y Y M M D D Y Y Y Y M M D D

5. Y Y Y Y M M D D Y Y Y Y M M D D

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.

Gamma glutamyl transferase was grade 3 elevated at baseline
last clinic visit. It has been rising since then, and
now is grade 4. ALP is only minimally elevated at 136.
ALT is 77. Denies alcohol abuse. HepBstg negative
GGT 581

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. STAVUDINE	60mg	ORAL	HIV	20051205	20120705	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. LAMIVUDINE	300mg	ORAL	HIV	20051205	20130928	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. EFVIREN2	600mg	ORAL	HIV	20051205	20130928	Unrelated	<input checked="" type="radio"/> Yes	None
						<input checked="" type="radio"/> Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								Stop
4. ATRILA	300/200/600	ORAL	HIV	20130928		Unrelated	<input checked="" type="radio"/> Yes	None
TDF/FTC/EFV						<input checked="" type="radio"/> Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								Stop
5. TENOFOVIR	300mg	ORAL	HIV	20120715	20130928	<input checked="" type="radio"/> Unrelated		None
						Poss. related	Yes	Reduce
						Cannot be assessed	<input checked="" type="radio"/> No	Interrupt
								<input checked="" type="radio"/> 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

8. SAE Outcome

- Died
- Unknown to date
- ☒ Ongoing ☐ Improved ☐ Recovered
- A complementary SAE notification must be submitted within 8 days
- Recovered → Date of recovery
- Recovered without sequelae
- or
- Recovered with sequelae
- Describe

Physician reporting SAE

Name

COLLINS IWHJI

Signature

[Signature]

Date form completed

2014 03 27