



TasP

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



00093282

Ukuphila kwami, ukuphila kwethu

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

SAE No.

SAE Visit Date

20140519.

Initial Notification Date

20140521.

Notification time

1. Patient details

TasP ID

24193.

Name

M.M

Sex

☒ Male

☐ Female

Date of birth

19540621

Enrolment date

20130417.

2. Measurements

Height

185 Cms

Last known: Weight

50.7

Kgs

Weight Date

201406140519.

CD4 count

666

CD4 Date

20140414.

Viral Load

85950

Viral Load Date

20131113.

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. UNWELL 20140520 20140519.

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 seen in trial clinic on 14/5/2014. He informed the nurse he was feeling unwell with weight loss. Associated dyspnoea. Refused referral to hospital. Doctor review was arranged for 20/5/2014 but said would not attend clinic as could not walk. Ambulance declined ambulance transfer to hospital. A tracker is being sent to his home.

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. ATRILA TDF/FTC/EFV	300/200/600 IV	HW		20140121		Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt Stop
2.						Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt Stop
3.						Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt Stop
4.						Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt Stop
5.						Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt Stop
6.						Unrelated	Yes	Reduce
						Poss. related	No	Interrupt Stop
						Cannot be assessed		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

UNABLE TO COMMENT

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

Signature

Imp

Date form completed

20140521