



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

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

00317429

SAE No.

SAE Visit Date

20160306

Initial Notification Date

20160308

Notification time

1400

1. Patient details

TasP ID

22643

Name

B.B.M.

Sex



Male

Female

Date of birth

19570911

Enrolment date

20130717

2. Measurements

Height

177 Cms

Last known: Weight

43.0

Kgs

Weight Date

20160120

CD4 count

251

CD4 Date

20160120

Viral Load

<40

Viral Load Date

20160120

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

Tick all that apply

- ☒ Resulted in death → Date of death 20160220 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 NameDate investigatorDate of onset of SAEbecame aware

1. Death 20160306 20160220

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.

Participant in control arm. CD4 251 & viral load suppressed on Atripla. He was last seen at trial clinic on 20/01/2016. He had been newly diagnosed with Diabetes & started on treatment by private doctor. Relatives reported that he had died suddenly at home on 20/02/2016. Cause of death is unclear.

DATA CAPTURE

2016-07-22

DCP - S

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. Tenofovir	300mg	oral	HIV	20130508		Unrelated Poss. related <input checked="" type="radio"/> Cannot be assessed	Yes No <input checked="" type="radio"/>	None Reduce Interrupt Stop
2. Emtricitabine	200mg	oral	HIV	20130508		Unrelated Poss. related <input checked="" type="radio"/> Cannot be assessed	Yes No <input checked="" type="radio"/>	None Reduce Interrupt Stop
3. Efavirenz	600mg	oral	HIV	20130508		Unrelated Poss. related <input checked="" type="radio"/> Cannot be assessed	Yes No <input checked="" type="radio"/>	None Reduce Interrupt Stop
4. Glibenclamide	5mg	oral	Diabetes	20160100		Unrelated Poss. related <input checked="" type="radio"/> Cannot be assessed	Yes No <input checked="" type="radio"/>	None Reduce Interrupt Stop
5.						Unrelated Poss. related Cannot be assessed	Yes No <input checked="" type="radio"/>	None Reduce Interrupt Stop
6.						Unrelated Poss. related Cannot be assessed	Yes No <input checked="" type="radio"/>	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

Cause of death unknown.
Patient reported to have been unwell.

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 GUG'EUHIE MUKHUSI

Signature

Date form completed 20160308