



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

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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



00125377

SAE No.

SAE Visit Date

20140918

Initial Notification Date

20140926

Notification time

1600

1. Patient details

TasP ID

40357

Name

~~G.C.G.~~ G.S

Sex

☒ Male

☐ Female

Date of birth

19490423

Enrolment date

20140828

2. Measurements

Height

178 Cms

Last known: Weight

65.7

Kgs

Weight Date

20140918

CD4 count

139

CD4 Date

20140828

Viral Load

<40

Viral Load Date

20140828

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

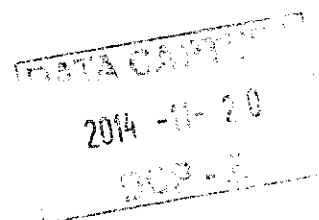
1. ^{Grade 3} Renal failure 20140923 20140918

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 newly enrolled in trial. CD4 139, suppressed viral load on Zidovudine, Lamivudine, Lopinavir/Ritonavir. Known hypertensive on treatment. Seen for raised creat (304) and urea (11.4). Referred to hospital, treated as out-patient. Urea worsened to 28 and creatine remained 300. Re-referred and admitted for IV fluid on 19/9/14. Improved clinically and discharged on 22/9/14.

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. Amlodipine | 10mg | oral | hypertension | 20140901 | | <input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed | <input checked="" type="radio"/> Yes <input type="radio"/> No | <input checked="" type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop |
| 2. Hydrochlorothiazide | 12.5mg | oral | hypertension | 20140901 | | <input type="radio"/> Unrelated <input checked="" type="radio"/> Poss. related <input type="radio"/> Cannot be assessed | <input type="radio"/> Yes <input type="radio"/> No | <input type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input checked="" type="radio"/> Stop |
| 3. Enalapril | 10mg | oral | hypertension | 20140901 | 20140901 | <input type="radio"/> Unrelated <input checked="" type="radio"/> Poss. related <input type="radio"/> Cannot be assessed | <input checked="" type="radio"/> Yes <input type="radio"/> No | <input type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input checked="" type="radio"/> Stop |
| 4. Lopinavir/Ritonavir | | oral | HIV | | | <input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed | <input type="radio"/> Yes <input checked="" type="radio"/> No | <input checked="" type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop |
| 5. Lamivudine | 300mg | oral | HIV | | | <input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed | <input type="radio"/> Yes <input checked="" type="radio"/> No | <input checked="" type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop |
| 6. Zidovudine | 400mg | oral | HIV | | | <input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed | <input type="radio"/> Yes <input checked="" type="radio"/> No | <input checked="" type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> 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

Participant is hypertensive -- risk of renal failure is high. Nephrologic treatment also may add to severity.

8. SAE Outcome

Died

Unknown to date

Ongoing

Improved

→ A complementary SAE notification must be submitted within 8 days

☒ Recovered → Date of recovery 20140922

Recovered without sequelae

or

Recovered with sequelae

→ Describe

Physician reporting SAE

Name Dr G. Michulisi

Signature

Date form completed 20140926