



TasP

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



00317472

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

Initial Notification Date 20 15 10 29

Notification time

14 55

1. Patient details

TasP ID

49362

Name

2.D

Sex

Male

☒ Female

Date of birth

19 88 03 05

Enrolment date

20 15 06 23

2. Measurements

Height

000 Cms

Last known: Weight

42.3

Kgs

Weight Date

20 15 09 14

CD4 count

141

CD4 Date

20 15 06 23

Viral Load

322572

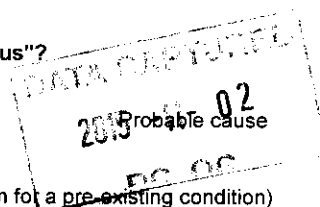
Viral Load Date

20 15 06 23

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

Tick all that apply

- ☐ Resulted in death → Date of death
- ☐ 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. Gastroenteritis 20 15 10 29 0000000000

2. Hypokalaemia 20 15 10 29 20 15 09 14

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 admitted at Hlabisa hospital 2/10/15 to 23/10/15 with acute gastroenteritis + hypokalaemia. Investigator was unaware of admission. Bloods taken in TasP on 14/11/15 show K⁺ 2.9, Na 134, Urea + creatinine normal. CD4 = 141. TasP clinic visit on 14/9/15 does not mention gastroenteritis, but did have cough. Patient will be followed up in TasP clinic.

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. Atropla | T | PO | HIV | 20150709 | | <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. Cotrimoxazole | Ti | PO | Prophylaxis | 20150623 | | <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 |
| 3. Amoxycillin | 1.5g | PO | Cough | 20150914 | 20150917 | <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 |
| 4. Vitamin B Co-strong | T | PO | unclear | 20150914 | 20151009 | <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 |
| 5. Paracetamol | 8lg | PO | Pain/chest infection | 20150914 | 20150924 | <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 |
| 6. | | | | | | <input type="radio"/> Unrelated <input 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 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?

This includes the patient's medical history

Yes ☒ No ☐

Describe

Patient is immunosuppressed. At risk of G.E.

8. SAE Outcome

Died

Unknown to date

Ongoing

Improved

→ A complementary SAE notification must be submitted within 8 days

☒ Recovered

→ Date of recovery 20151023

Recovered without sequelae

or

Recovered with sequelae

→ Describe

Physician reporting SAE

Name

MELANIE HILL

Signature

[Signature]

Date form completed

20151029