



TasP

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



00125361

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

20140624

Initial Notification Date

20140624

Notification time

1000

1. Patient details

TasP ID

22641

Name

T. M

Sex

Male

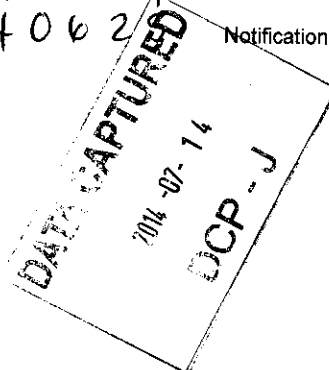
☒ Female

Date of birth

19730708

Enrolment date

20130712



2. Measurements

Height

140 Cms

Last known: Weight

63.1

Kgs

Weight Date

20140624

CD4 count

102

CD4 Date

20140506

Viral Load

121

Viral Load Date

20140515

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. Severe Anaemia 20140624 20140620

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 on AZT, 3TC and efavirenz. Presents with dyspnea on mild exertion, fatigability and palpitations. Full blood count taken, Haemoglobin 4.7 g/dL. Patient referred to hospital urgently for blood transfusion. Zidovudine stopped.

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. Zidovudine	400mg	oral	HIV	20140520	20140624	Unrelated Poss. related Cannot be assessed	<input checked="" type="radio"/> Yes <input type="radio"/> No	None Reduce Interrupt Stop
2. Lamivudine	300mg	oral	HIV	20140328		Unrelated Poss. related Cannot be assessed	<input checked="" type="radio"/> Yes <input type="radio"/> No	None Reduce Interrupt Stop
3. Efavirenz	600mg	oral	HIV	20140328		Unrelated Poss. related Cannot be assessed	<input checked="" type="radio"/> Yes <input type="radio"/> No	None Reduce Interrupt Stop
4. RIF / INH	300/150mg	oral	PTB	20140514		Unrelated Poss. related Cannot be assessed	<input checked="" type="radio"/> Yes <input type="radio"/> No	None Reduce Interrupt Stop
5. Pyridoxine	25mg	oral	Prophylaxis	20140314		Unrelated Poss. related Cannot be assessed	<input checked="" type="radio"/> Yes <input type="radio"/> No	None Reduce Interrupt Stop
6. Cotrimoxazole	960mg	oral	Prophylaxis	20140328		Unrelated Poss. related Cannot be assessed	<input checked="" type="radio"/> Yes <input type="radio"/> No	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? ☒ 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

Date of recovery

Recovered without sequelae

or

Recovered with sequelae

Describe

Physician reporting SAE

Name DR G. Mkhulisi

Signature

Date form completed 20140625

