



TasP

Antiretroviral Treatment as Prescribed - ANRS 12249
(Shedding blood, no pain, no death for our health)

Ukuphila kwami, ukuphila kwethu
Africa Centre TasP Trial

Egedeni

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

SAE No.

SAE Visit Date

2013 09 07

Initial Notification Date

2013 09 11

Notification time

1000

1. Patient details

TasP ID

28520

Name

S. B

Sex

Male

Female

Date of birth

19 40 03 03

Enrolment date

20 13 05 14

DATA CAPTURED

2013 -10- 29

DC QC

2. Measurements

Height

175 Cms

Last known: Weight

74.9

Kgs

Weight Date

2013 08 08

CD4 count

194

CD4 Date

20 13 08 08

Viral Load

1533 000

Viral Load Date

20 13 05 25

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. CONGESTIVE
CARDIAC
FAILURE 2013 09 11 2013 09 07

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.

Known HIV / CCF / Chronic renal impairment on treatment.
Patient was last seen at TasP clinic on 23/08/2013.
on 07/09/2013, patient called the TasP nurse to
organise an ambulance to take him to hospital
as he was not feeling well. Patient was later
admitted the same day at Heabisa Hospital.

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. Hydrochlorothiazide	45mg	oral	HPT	UNKNOWN	20130615	<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input checked="" type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input checked="" type="radio"/> No	<input type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
NB: Drug stopped as patient switched to furosemide								
2. Furosemide	40mg	oral	HPT/CCF	20130530		<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input checked="" type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input checked="" type="radio"/> No	<input type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
3. Spironolactone	25mg	oral	CCF	20130729		<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input checked="" type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input checked="" type="radio"/> No	<input type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
4. Enalapril	15mg	oral	HPT/CCF	UNKNOWN	20130715	<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input checked="" type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input checked="" type="radio"/> No	<input type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
NB: Drug stopped because of Chronic renal impairment								
5. Atorlipa	20mg 200mg 600mg	oral	HPT	UNKNOWN	20130715	<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input checked="" type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input checked="" type="radio"/> No	<input type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
6. ABC 300mg STC 150mg EFV 600mg		oral	HPT	UNKNOWN	20130823	<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input checked="" type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input checked="" 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

known HPT / CCF / Chronic renal failure

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 NGANDU OSEE BETHUNA

Signature

Date form completed 20130912