



TasP

Antiretroviral Treatment as Prevention - ANRS 12249  
(Ukaphila kwami, ukaphila kwethu)

Ukaphila kwami, ukaphila kwethu

Africa Centre TasP Trial

Serious Adverse Event Reporting

ANRS 12249 Initial SAE Notification

SAE-AI



00317479

Completed forms must be sent to  
ANRS within 48 hrs.  
Email: [pharmacovigilance@anrs.fr](mailto:pharmacovigilance@anrs.fr)  
Fax: +33 153 946 002

SAE No.

SAE Visit Date

20 15 06 18

Initial Notification Date

20 15 11 17

Notification time

14 20

1. Patient details

TasP ID

4 6 2 3 7

Name

Z.G.

Sex

Male

Female

Date of birth

1 9 6 2 10 30

Enrolment date

20 1 3 10 14

DATA CAPTURED

2015 -11- 17

2. Measurements

Height

UUU Cms

Last known: Weight

92.3

Kgs

Weight Date

20 15 07 20

CD4 count

682

CD4 Date

20 15 04 21

Viral Load

<40

Viral Load Date

20 15 01 15

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. Multiple Myeloma 20 15 11 16 20 15 08 05

2. #Arm + leg 20 15 11 16 20 15 08 05

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.

This patient was seen at TasP clinic 18/06/2015 with a cough + fever (for 3/7) and left shoulder pain (for 4/7). On examination her left clavicular head was protruding. She denied trauma. She was referred to Hlabisa hospital for X-ray and opinion on the clavicle. She was seen as an outpatient. On her way back from hospital she fell over and fractured her arm and a leg (fracture details unclear). She went back to Hlabisa, and was referred from there to NGZ hospital. NGZ hospital diagnosed her with multiple myeloma. She is now receiving chemotherapy at NGZ.

## 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. Atrisin	1	PO	HIV	20 14 10 23		<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. HCTZ	12.5mg	PO	Hypertension	20 09 01 01		<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. Aspirin	150mg	PO	Secondary prophylaxis	20 14 10 13		<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. folic acid	5mg	PO	Anaemia	20 15 02 12	20 15 03 12	<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. Isoniazid	300mg	PO	TB prophylaxis	20 14 10 13	20 15 06 18	<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. Ferrous Sulphate	200mg	PO	Anaemia	20 15 02 12	20 15 03 12	<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?

This includes the patient's medical history

Yes ☒ No ☐  
Describe

Patient at risk of cancer regardless of participation in research.

## 8. SAE Outcome

Died

Unknown to date

Ongoing

Improved

☒ Recovered

→ A complementary SAE notification must be submitted within 8 days

→ Date of recovery 20 15 10 07

☒ Recovered without sequelae  
or

☐ Recovered with sequelae

→ Describe

Discharged from hospital as an inpatient.

## Physician reporting SAE

Name MELANIE HILL

Signature

Date form completed 20 15 11 17