



TasP

Antiretroviral Treatment as Prevention - ANRS 12249  
Ukuphila kwami, ukuphila kwethu

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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](mailto:pharmacovigilance@anrs.fr)  
Fax: +33 153 946 002



00125390

SAE No.

SAE Visit Date

2014 11 11

Initial Notification Date

2014 11 28

Notification time

1000

#### 1. Patient details

TasP ID

34639

Name

E.S.

Sex

Male

Female

Date of birth

19590508

Enrolment date

20140805

#### 2. Measurements

Height

165 Cms

Last known: Weight

74.9

Kgs

Weight Date

2014 11 11

CD4 count

497

CD4 Date

2014 08 18

Viral Load

<40

Viral Load Date

2014 08 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

PHOTO CAPTURED

2015-01-09

1 - 1000

#### 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

2014 11 26

2014 11 11

2. Weight loss

2014 11 26

2014 11 11

3. Renal failure

2014 11 27

2014 11 13

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 is known type 2 diabetes and HIV positive. She attended TasP clinic on 2014/11/11 complaining of vomiting. She was transferred to a government clinic to wait for an ambulance transfer to Hlabisa hospital. She was admitted to hospital on 2014/11/13. I reviewed her in hospital on 27/11/14. Her admission creatinine was 668. Despite IV fluids and resolution of the diarrhoea + vomiting on 23/11/14 her creatinine was 1214. She is still admitted, complementary information to follow.

## 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. Atripla	1 tablet	PO	HIV	2014 09 02	2014 11 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	None Reduce Interrupt Stop
2. Hydrochlorothiazide	12.5mg	PO	hypertension	2014 11 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	None Reduce Interrupt Stop
3. Metformin	1g	PO	Diabetes	2014 11 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	None Reduce Interrupt Stop
4. Aspirin	150mg	PO	21 <sup>st</sup> prevention	2014 11 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	None Reduce Interrupt Stop
5.						<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input type="radio"/> No	None Reduce Interrupt 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	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?

This includes the patient's medical history

☒ Yes ☐ No

Describe

The patient is immunocompromised and at risk of gastroenteritis.

## 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 McLANIE HILL

Signature 

Date form completed 2014 11 28