



TasP

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



00317485

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

SAE No.

SAE Visit Date

20 15 11 10

Initial Notification Date

20 15 12 02

Notification time

10 30

### 1. Patient details

TasP ID

53732

Name

J.M.M.

Sex

☒ Male

☐ Female

Date of birth

19 57 03 21

Enrolment date

20 15 04 15

### 2. Measurements

Height

163 Cms

Last known: Weight

70.9

Kgs

Weight Date

20 15 11 10

CD4 count

575

CD4 Date

20 15 11 10

Viral Load

19481

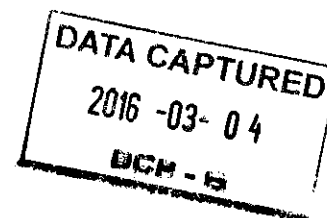
Viral Load Date

20 15 04 29 → Pre-ART

### 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. Grade 4 GGT 20 15 11 30 20 15 11 10

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.

Routine TasP bloods taken 10/11/15 show ALT 135, ALP 168 GGT 907 → grade 4. The only other LFT's for this patient are his baseline LFT's that are entirely normal. However, patient is known to abuse alcohol. Nurse says he smells of alcohol on day bloods were taken. Patient was contacted for M.O review, but is working out of area + feels well so declined to come.

## 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. Atropine	T	PO	HIV	20150525		Unrelated	<input checked="" type="radio"/> Yes	<input checked="" type="radio"/> None
						<input checked="" type="radio"/> Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								Stop
2. HCTZ	12.5mg	PO	hypertension	20150415		Unrelated	<input checked="" type="radio"/> Yes	<input checked="" type="radio"/> None
						<input checked="" type="radio"/> Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								Stop
3. Enalapril	20mg	PO	hypertension	20150415		Unrelated	<input checked="" type="radio"/> Yes	<input checked="" type="radio"/> None
						<input checked="" type="radio"/> Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								Stop
4. Amlodipine	10mg	PO	hypertension	20150415		Unrelated	<input checked="" type="radio"/> Yes	<input checked="" type="radio"/> None
						<input checked="" type="radio"/> Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								Stop
5.						Unrelated		None
						<input checked="" type="radio"/> Poss. related	Yes	Reduce
						Cannot be assessed	No	Interrupt
								Stop
6.						Unrelated		None
						<input checked="" type="radio"/> Poss. related	Yes	Reduce
						Cannot be assessed	No	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

likely to be related to alcohol consumption

## 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

MELANIE HILL

Signature

*[Signature]*

Date form completed

20151202