



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

00317470

SAE No.

SAE Visit Date

Initial Notification Date

20151026

Notification time

0930

#### 1. Patient details

TasP ID

40920

Name

N.M.

Sex

Male

Female

Date of birth

12/9/54

Enrolment date

20150622

#### 2. Measurements

Height

170 Cms

Last known: Weight

50.2

Kgs

CD4 count

504

Viral Load

<40

DATA ON FILE

2015-10-26

Weight Date

20150929

CD4 Date

20150622

Viral Load Date

20150706

#### 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. Raised GGT 20150909 20150622

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.

Patient transferred into TasP with deranged LFT. Has been taking ART since 2007. Was reviewed in TasP by M.O. in June 2015. Noted to abuse alcohol: taking homebrewed traditional beer. At that time TFT normal; Hepatitis A, B + C negative. Bloods taken 7/10/15 show ALT 90, ALP 112, GGT 504. Clinic entry on 29/9/15 said patient was clinically well.

## 6. Medications

List all drugs taken (or prescribed) before occurrence of SAE

	Generic Name	Daily dose	Route of administration	Indication	Date started	Causality assessment	Expected reaction? (BNF/SPC)	Action taken
					Date stopped			
1.	Atorlip	T	PO	HIV	20150630	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.						Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								Stop
3.						Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								Stop
4.						Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								Stop
5.						Unrelated		None
						Poss. related	Yes	Reduce
						Cannot be assessed	No	Interrupt
								Stop
6.						Unrelated		None
						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

Most likely cause of deranged LFT is alcohol.

## 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 

Date form completed 20151026