



TasP

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



00317468

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
Fax: +33 153 946 002

SAE No.

SAE Visit Date

Initial Notification Date

20 15 10 22

Notification time

15 10

1. Patient details

TasP ID

33868

Name

H.M.G

Sex

Male

☒ Female

Date of birth

19940209

Enrolment date

20140814

2. Measurements

Height

165 Cms

Last known: Weight

68.9

Kgs

Weight Date

20150930

CD4 count

436

CD4 Date

20150820

Viral Load

9408

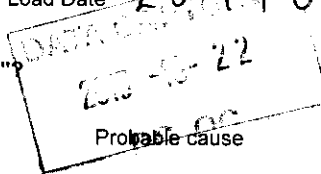
Viral Load Date

20140818

3. By which criteria is this adverse event considered to be "Serious"?

Tick all that apply

- ☐ Resulted in death → Date of death
- ☐ 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. Deranged LFT 20151005 20150820

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 had normal LFT's pre-ART. Commenced atipravir 22/4/15.
By August 2015 ALT 140 U/L, ALP 440 U/L, GGT 764 U/L.
Only risk factor for liver problems is newly initiated ART.
Bloods taken 29/9/15 show ALT 58, ALP 458, GGT 680. Referred for USS
& abdomen at Hlabisa hospital on 30/9/15. Patient reports USS was normal.

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.	Atropin	1	po	HIV	20150422	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

Patient was eligible for ART regardless of being in the trial.

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 20151022