



TasP

Anonymous 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
Fax: +33 153 946 002



00317461

SAE No.

SAE Visit Date

20150729

Initial Notification Date

20150828

Notification time

1003

1. Patient details

TasP ID

27396

Name

M.B.M

Sex



Male

Female

Date of birth

19690320

Enrolment date

20130314

2. Measurements

Height

178

Cms

Last known: Weight

69.2

Kgs

Weight Date

20150824

CD4 Date

20150729 (ERROR)

CD4 count

474

Viral Load

<40

Viral Load Date

20150729

20150811

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

Date of onset of SAE

became aware

1. Grade 4 deranged GGT. 20150803 20150729

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 routine bloods taken on 29/7/15 which showed a new deranged LFT with GGT 1196, grade 4 event. He was reviewed by the M.O in clinic on 24/8/15. He was clinically well with an unremarkable examination. He did have an episode of severe diarrhoea (lasted 7/7) around the time the bloods were taken. He also drinks alcohol to excess at weekends. His LFT will be monitored in TasP clinic.

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. TDF/FTC/EFV	1	PO	HLV	20140509		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. hydrochlorothiazide	12.5mg	PO	hypertension	20131205		<input checked="" type="radio"/> Unrelated	Yes	<input checked="" type="radio"/> None
						Poss. related	<input checked="" type="radio"/> No	Reduce
						Cannot be assessed		Interrupt Stop
3. Enalapril	10mg	PO	hypertension	20131205		<input checked="" type="radio"/> Unrelated	Yes	<input checked="" type="radio"/> None
						Poss. related	<input checked="" type="radio"/> 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? ☒ Yes ☐ No
This includes the patient's medical history
Describe

8. SAE Outcome

Died

Unknown to date

Ongoing

Improved

→ A complementary SAE notification must be submitted within 8 days

☒ Recovered

→ Date of recovery 20150824

☒ Recovered without sequelae
or

Recovered with sequelae

Describe

Physician reporting SAE

Name MELANIE HILL

Signature

Date form completed 20150828