



TasP

Antiretroviral Treatment as Prevention (ANRS 12249)

(Ukaphila kwami, ukuphila kwethu)



00317473

Ukaphila 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

20151026

Initial Notification Date

20151029

Notification time

1530

1. Patient details

TasP ID

51041

Name

NQM.

Sex



Male

Female

Date of birth

19670721

Enrolment date

20150413

2. Measurements

Height

UUU Cms

Last known: Weight

51.7

Kgs

CD4 count

535

Viral Load

<40

Weight Date

2015-10-26

CD4 Date

2015-10-26

Viral Load Date

2015-10-26

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 raised GGT 20151026 20150415

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 has a persistently raised GGT >10 ULN = grade 4 event (since entry into the study on atazanavir, epileptic on sodium valproate and a chronic TasP.)
alcoholic, drinking 2 litres/day of home brewed beer.

He is clinically well, with no jaundice, no organomegaly on abdominal examination.

His GGT is likely to remain high.

13/4/15 GGT = 730 (other LFT's normal)

20/7/15 GGT = 608

12/10/15 GGT = 468

NB - GGT was elevated before starting epilepsy

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	T	PO	HIV	20150428		Unrelated ● Poss. related Cannot be assessed	● Yes No	● None Reduce Interrupt Stop
2. Eplim	1.2g	PO	epilepsy	20150421		Unrelated ● Poss. related Cannot be assessed	● Yes No	● None Reduce Interrupt Stop
3. Isoniazid	300mg	PO	TB prophylaxis	20150914		Unrelated ● Poss. related Cannot be assessed	● Yes No	● None Reduce Interrupt Stop
4. Pyridoxine	25mg	PO	Peripheral neuropathy prevention	20150914		Unrelated Poss. related Cannot be assessed	Yes ● No	● None Reduce Interrupt Stop
5.						Unrelated Poss. related Cannot be assessed	Yes No	None Reduce Interrupt Stop
6.						Unrelated Poss. related Cannot be assessed	Yes 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

Patient had damaged UT prior to Tmp. history alcohol is the main contributor

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

20151029