



TasP

Antiretroviral Treatment as Prevention - ANRS 12249
Ukaphila kwami, ukuphila kwethu

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Africa Centre TasP Trial

Serious Adverse Event Reporting

ANRS 12249 Initial SAE Notification

SAE-AI



00057407

Completed forms must be sent to
ANRS within 48 hrs.
Email: pharmacovigilance@anrs.fr
Fax: +33 153 946 002

SAE No.

SAE Visit Date

2013 07 25

Initial Notification Date

2013 07 29

Notification time

1. Patient details

TasP ID

16966

Name

Sex

Male

☒ Female

Date of birth

19790621

Enrolment date

2013 01 14

2. Measurements

Height

159 Cms

Last known: Weight

95.7

Kgs

Weight Date

2013 07 24

CD4 count

518

CD4 Date

2013 05 30

Viral Load

< 50

Viral Load Date

2013 05 30

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. DRUG INDUCED 2013 07 26 2013 07 25
HEPATITIS

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.

Started Atripla on 7/3/2013. ALT normal prior to initiation of ART. In May 2013 ALT 9135 with normal Bilirubin. Presented to trial clinic with jaundice and dark urine on 22/7/2013. ALT 256, Total Bil 103, Conj Bil 62. Atripla discontinued and Kaletra monotherapy prescribed. Repeat bloods on 25/7/2013 reported on 26/7/2013, ALT 468, Total Bil 124, Conj Bil 72. Kaletra discontinued on 27/7/2013.

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. AZIDRA TDF/FTC/EFV	300/200/600 PO	PO	HIV	20130307	20130722	Unrelated Poss. related Cannot be assessed	<input checked="" type="radio"/> Yes No	None Reduce Interrupt Stop
2. ISONIAZID	300mg	PO	TB PROPHYLAXIS	20130627	20130722	Unrelated Poss. related Cannot be assessed	<input checked="" type="radio"/> Yes No	None Reduce Interrupt Stop
3. PYRIDOXINE	25mg	PO	NEUROPATHY PROPHYLAXIS	20130627	20130722	Unrelated Poss. related Cannot be assessed	Yes <input checked="" type="radio"/> No	None Reduce Interrupt Stop
4. VIT B12	T	PO	SUPPLEMENT	20130307	20130722	Unrelated Poss. related Cannot be assessed	Yes <input checked="" type="radio"/> No	None Reduce Interrupt Stop
5. KALETRA LOPINAVIR/RIT	800/200	PO	HIV	20130722	20130727	Unrelated Poss. related Cannot be assessed	<input checked="" type="radio"/> 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? ☐ Yes ☒ No

This includes the patient's medical history

Describe

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

COLLINS JHUTTI

Signature

[Signature]

Date form completed

20130729