



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

2012-07-08
00-20-2107

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



00008818

SAE No.

156

SAE Visit Date

20120618

Initial Notification Date

20120619

Notification time

1500

1. Patient details

TasP ID

15647

Name

M.D

Sex

☐ Male

☒ Female

Date of birth

19500412

Enrolment date

20120523

2. Measurements

Height

157 Cms

Last known: Weight

30.00 Kgs

Weight Date

20120618

CD4 count

95

CD4 Date

20120606

Viral Load

<300

Viral Load Date

20120606

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

ACUTE RENAL FAILURE

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. Severe diarrhoea 20120618 20120101

2. Acute Renal Failure 20120618 20120606

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 had diarrhoea for 5 months. Switched in March 2012 from NAT/3TC/EFV to TDF/3TC/EFV in previous health facility. At baseline visit to trial clinic, she was very dehydrated, tachycardic and unwell. Baseline Creatinine 6/6/12 was 1208 umol/l. Transferred to nearby Rix Health care facility for fluid resuscitation but declined escalation to hosp for admission. Eventually accepted admission 19/6/2012

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. STAVUDINE	60mg	Oral	HIV	20071208	20120316	<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
2. LAMIVUDINE	300mg	Oral	HIV	20071208	20120618	<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input checked="" type="radio"/> Stop
3. EFVIREN2	600mg	Oral	HIV	20071208	20120618	<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input checked="" type="radio"/> Stop
4. TENOFOVIR	300mg	Oral	HIV	20120316	20120618	<input type="radio"/> Unrelated <input checked="" type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input checked="" type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input checked="" type="radio"/> 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

Severe diarrhoea and Renal failure pre-dated baseline clinic visit. Severe diarrhoea must have resulted in pre-renal failure with additional nephrotoxicity from Tenofovir.

8. SAE Outcome

☐ 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 RICHARD LESSELLS

Signature

Date form completed 20120620