



TasP

Accelerated Treatment of HIV in Africa - ANRS 12249
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Ukuphila kwami, ukuphila kwethu

Africa Centre TasP Trial

Serious Adverse Event Reporting

ANRS 12249 Initial SAE Notification

SAE-AI

23 Jan 2013



00093288

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

SAE No.

SAE Visit Date

20140424

Initial Notification Date

20140425

Notification time

1. Patient details

TasP ID

22313, 22131

Name

B.M.

Sex

☒ Male

☐ Female

Date of birth

19610125

Enrolment date

20131007

2. Measurements

Height

165 Cms

Last known: Weight

40.5

Kgs

Weight Date

20140414

CD4 count

105

CD4 Date

20140313

Viral Load

48

Viral Load Date

20140313

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

Tick all that apply



Resulted in death

→ Date of death

20140422

Probable cause

ACUTE RENAL FAILURE



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. ACUTE RENAL FAILURE 20140424 20140414

2. ...

3. ...

4. ...

5. ...

DATA CAPTURED
2014-06-05
DCP - J

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 was initially on D4T/3TC/EFV. On the 14/4/2014, gave a history of admission to hospital for 3 days with diarrhoea. Was switched to Atripla on 14/4/2014, U/E done on the same day. Results of U/E done on 14/4/2014 when started Atripla showed Metabolic acidosis, severe hypokalaemia and Creatinine of 342.

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	PO	HIV	20080302	20140414	<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
2. LAMIVUDINE	300MG	PO	HIV	20080302	20140414	<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
3. EFAVIRENZ	600MG	PO	HIV	20080302	20140414	<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
4. ATRIPLA TDF/FTC/EFV	300/200/600	PO	HIV	20140414		<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
5.						<input 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
6.						<input 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

DATA CAPTURED
7/14/06-06
DCP 4 J

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

Patient developed severe diarrhoea and acute renal failure prior to Atripla. Revealed by blood test done on same day started Atripla. Atripla could have exacerbated the acute renal failure

8. SAE Outcome

☒ Died

☐ Unknown to date

☐ Ongoing

☐ Improved

☐ Recovered

→ A complementary SAE notification must be submitted within 8 days

→ Date of recovery Y Y Y Y M M D D

☐ Recovered without sequelae

or

☐ Recovered with sequelae

Describe

Physician reporting SAE

Name

Signature

Date form completed

COLLINS INWYR
Xmp

20140425