



TasP

Antiretroviral Treatment as Prevention - ANRS 12249
(Uso de antiretrovirais para a prevenção da infecção pelo HIV)



00057532

Ukuphila kwami, ukuphila kwethu

Africa Centre TasP Trial

Serious Adverse Event Reporting

ANRS 12249 Initial SAE Notification

Madwaleni

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

20130717

Initial Notification Date

20130718

Notification time

1. Patient details

TasP ID

16794

Name

S.M

Sex

Male

☒ Female

Date of birth

19710101

Enrolment date

20120926

2. Measurements

Height

162 Cms

Last known: Weight

74.0

Kgs

Weight Date

20130717

CD4 count

247

CD4 Date

20130328

Viral Load

<50

Viral Load Date

20130328

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. Gall stones 20130717 20130705

2.

3.

4.

5.

DATA CAPTURE

2013-07-24

BCP - S

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.

Admitted to hospital on 05/07/2013, diagnosed with gall stones and discharged on 15/07/2013. Treated with antibiotics

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. TENOFOVIR	300mg	PO	HW	20110421		<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input checked="" type="radio"/> No	<input checked="" type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
2. LAMIVUDINE	300mg	PO	HW	20110421		<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input checked="" type="radio"/> No	<input checked="" type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
3. EFVIRENZ	600mg	PO	HW	20110421		<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input checked="" type="radio"/> No	<input checked="" type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
4.						<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
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

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

Gall stones.

8. SAE Outcome

Died

Unknown to date

Ongoing

Improved

A complementary SAE notification must be submitted within 8 days

☒ Recovered

Date of recovery 20130715.

Recovered without sequelae

or

Recovered with sequelae

Describe

Physician reporting SAE

Name

COLLINS IHWJ

Signature

Xup

Date form completed

20130718