



TasP

Antiretroviral Treatment as Prevention - ANRS 12249  
(Ukaphila kwami, ukuphila kwethu (my health for our health))



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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](mailto:pharmacovigilance@anrs.fr)  
Fax: +33 153 946 002

SAE No.

SAE Visit Date

20130208

Initial Notification Date

20130220

Notification time

1715

1. Patient details

TasP ID

19455

Name

Z. G

Sex

Male

Female

Date of birth

19820602

Enrolment date

20130208

2. Measurements

Height

159 Cms

Last known: Weight

62.0

Kgs

Weight Date

20130208

CD4 count

53

CD4 Date

20130208

Viral Load

Viral Load Date

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. HEPATITIS 20130215 20130208

2. 1715 1715 1715 1715 1715 1715 1715 1715 1715 1715

3. 1715 1715 1715 1715 1715 1715 1715 1715 1715 1715

4. 1715 1715 1715 1715 1715 1715 1715 1715 1715 1715

5. 1715 1715 1715 1715 1715 1715 1715 1715 1715 1715

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.

New HIV diagnosis on 04/02/2013. Abnormal LFTs discovered on routine baseline bloods. Asymptomatic. Hepatitis B positive. To start ART with repeat LFTs in one week. Viral load results outstanding.

## 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.	/						<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
2.	/						<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
3.	/						<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
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 checked="" 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?

This includes the patient's medical history

☒ Yes  
☐ No  
 Describe

Baseline revealed Hepatitis BSAg Positive. Further information not available

## 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

*[Signature]*

Date form completed

20130220