



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

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Africa Centre TasP Trial

SAE-AI

Serious Adverse Event Reporting

ANRS 12249 Initial SAE Notification

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



00125363

SAE No.

SAE Visit Date

20140708

Initial Notification Date

20140714

Notification time

1600

1. Patient details

TasP ID

31565

Name

O.B.M.

Sex

☒ Male

☐ Female

Date of birth

19591225

Enrolment date

20140627

2. Measurements

Height

173 Cms

Last known: Weight

77.00

Kgs

Weight Date

20140708

CD4 count

140

CD4 Date

20140701

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
- ☐ 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

DATA CAPTURE
Probable cause
2014-07-16
DCP-8

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
Grade 2 1. Renal failure	20140714	20140703
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.

The patient attended TasP clinic on 2014/07/01 for a baseline visit. He was ambulant and reported no problems. However, the routine baseline blood tests taken on 2014/07/01 revealed a renal failure with urea of 12.4 and Creatinine 302. As soon as this was discovered he was referred to hospital. He is known to have hypertension. Blood Pressure on 8/7/14 was 156/100. Blood results were seen on 2014/07/03. Patient only attended hospital on 14/07/14

6. Medications

List all drugs taken (or prescribed) before occurrence of SAE

	<u>Generic Name</u>	<u>Daily dose</u>	<u>Route of adminis- tration</u>	<u>Indication</u>	<u>Date started</u>	<u>Causality assessment</u>	<u>Expected reaction?</u> (BNF/SPC)	<u>Action taken</u>
					<u>Date stopped</u>			
1.						Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt Stop
2.						Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt Stop
3.						Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt Stop
4.						Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt Stop
5.						Unrelated		None
						Poss. related	Yes	Reduce
						Cannot be assessed	No	Interrupt Stop
6.						Unrelated		None
						Poss. related	Yes	Reduce
						Cannot be assessed	No	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 → Date of recovery
Recovered without sequelae
or
Recovered with sequelae
→ Describe

Physician reporting SAE

Name MURRAY HILL

Signature 

Date form completed 2014 0715