



TasP

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

Ukaphila kwami, ukuphila kwethu

Endings

SAE-AC

Africa Centre TasP Trial

Serious Adverse Event Reporting



00199207

ANRS 12249 Complementary SAE Notification

Completed forms must be sent to
ANRS within 8 days.
Email: pharmacovigilance@anrs.fr
Fax: +33 153 946 002

SAE No.

Initial Notification Date

2014 07 14

i.e. Date of original Initial Notification Form

Complementary Notification Date

2014 08 06

1. Patient details

TasP ID

31565

Name

O.B.M.

Sex

☒ Male

☐ Female

Date of birth

1959 12 25

Enrolment date

2014 06 27

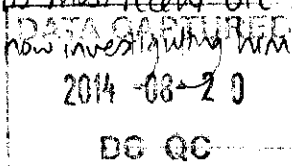
2. Description of the reported SAE

The patient attended for a baseline clinic visit on 1/7/14. The routine blood tests revealed renal failure - Creatinine 302, Urea 12.9. He was referred immediately to hospital on 3/7/14, for further investigation, but only attended the hospital on 8/7/14.

Date of SAE onset 2014 07 03

3. Complementary information

His is known to be hypertensive. Unfortunately the patient was not investigated at hospital. He did not have an ultrasound or any additional tests except FBC and U+e. He had IV fluid. He was discharged from hospital on 29/7/14. His most recent U+e's were from 23/7/14 showing urea 12.0 and creatinine 253. We are now investigating him as an outpatient.



4. New diagnosis?

Yes → Describe

☒ No

Date of new diagnosis

5. Patient treatment

a) Did the event resolve after discontinuation of treatment?

Yes

No

☒ N/A

→ Which treatment?

Date discontinued

b) Did the event reappear after reintroduction of treatment?

Yes

No

☒ N/A

→ Which treatment?

Date reintroduced

c) Has the complementary information mentioned above modified your judgement of causality regarding one or more treatments compared to your initial notification?

Yes → Section 6

☒ No → Section 7

6. Medications

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

Generic Name	Dose	Frequency	New judgement of causality
1.			Unrelated Poss. related Cannot be assessed
2.			Unrelated Poss. related Cannot be assessed
3.			Unrelated Poss. related Cannot be assessed
4.			Unrelated Poss. related Cannot be assessed

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 is a defaulter of ART and HCTZ. He is currently on ~~ART~~ neither. His renal failure was discovered at baseline, so unlikely due to participation in Tasp.

8. SAE Outcome

Death → Date of death Probable Diagnosis _____

Unknown to date

Ongoing → Another complementary SAE notification form must be submitted.

Improved

Worsened

☒ Recovered → Date of recovery 2014 07 29

Recovered without sequelae

or

☒ Recovered with sequelae

Describe Deemed medically fit for discharge, but renal function still deranged. Cause unknown.

Physician reporting SAE Complementary Notification

Name MELANIE HILL

Signature *Mx*

Date form completed 2014 08 06