



TasP

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



00317465

Ukuphila 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
Fax: +33 153 946 002

SAE No.

SAE Visit Date

20151021

Initial Notification Date

20151022

Notification time

1310

1. Patient details

TasP ID

40357

Name

G.S

Sex



Male

Female

Date of birth

19490423

Enrolment date

20140828

2. Measurements

Height

178 Cms

Last known: Weight

74.4

Kgs

Weight Date

20151007

CD4 count

197

CD4 Date

20150902

Viral Load

<40

Viral Load Date

20150911

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. Renal failure 20151021 20150915

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.

Known Chronic Renal failure. Usual Creatinine is 350-400 umol/L.
On 15/9/15 Creat. had risen to 681. On 1/10/15 Creat was 713, Urea 23.8.
(Referred to Hlabisa hospital who sent him home.) On 21/10/15 Creat was 1082
Urea 31.1. Referred urgently back to Hlabisa hospital
△ Acute on Chronic renal failure. ? Secondary to diarrhoea.

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. AZT	600mg	PO	HIV	20141016	2	<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input checked="" type="radio"/> Yes <input type="radio"/> No	<input checked="" type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
2. ZTC	150mg	PO	HIV	20141016		<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input checked="" type="radio"/> Yes <input type="radio"/> No	<input checked="" type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
3. Aluvia	TIII	PO	HIV	20141016		<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input checked="" type="radio"/> Yes <input type="radio"/> No	<input checked="" type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
4. HCTZ	12.5mg	PO	Hypertension	20140101		<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input checked="" type="radio"/> Yes <input type="radio"/> No	<input checked="" type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
5. Amloriphe	20mg	PO	Hypertension	20140901		<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input checked="" type="radio"/> Yes <input type="radio"/> No	<input checked="" 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?

This includes the patient's medical history

Yes ☒ Describe

No ☐ Patient at risk of diarrhoea as immunosuppressed and on aluvia. Unrelated to research.

8. SAE Outcome

☐ Died
☐ Unknown to date
☒ Ongoing ☐ A complementary SAE notification must be submitted within 8 days
☐ Improved
☐ Recovered ☐ Date of recovery
 Recovered without sequelae
 or
 Recovered with sequelae
 ☐ Describe

Physician reporting SAE

Name

MELANIE HILL

Signature

[Signature]

Date form completed

20151022