



TasP

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

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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

00317450

SAE No.

SAE Visit Date

20150122

Initial Notification Date

20150213

Notification time

1540

1. Patient details

TasP ID

30783

Name

PMM.

Sex



Male

Female

Date of birth

19620213

Enrolment date

20130708

2. Measurements

Height

Cms

Last known: Weight

43.3

Kgs

Weight Date

20150122

CD4 count

224

CD4 Date

20140721

Viral Load

193

Viral Load Date

20140721

3. By which criteria is this adverse event considered to be "Serious"?

Tick all that apply



Resulted in death

→ Date of death

20150208

Probable cause

?Gastroenteritis?



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. Weight loss 20150122 201412
2. Psychomotor Slowing 20150122 201412
3. Psychosis 20150122 201412
4. Gastroenteritis 20150212 201502
5. Death 20150212 20150208

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.

After refusing to attend clinic for some months, he attended on 22/1/15 where he was seen by the TasP doctor. He had lost weight (56.8kg August 2014; 43.3kg at that visit). His sister gave a history of psychotic symptoms for 2 months, including talking to himself. He had psychomotor slowing. He was referred to Hlabisa hospital for a TB and psychiatric work-up, plus LP in case of insidious meningitis. He did attend hospital, but was discharged on 2/2/15. Between discharge and his death at home on 8/2/15 the ~~patient~~ (error) family report that he had diarrhoea + vomiting.

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. Atripla	One tablet po		HIV	20130824		<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.						<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 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?

This includes the patient's medical history

Yes ☒ No ☐
Describe

The patient was immunocompromised and at risk of opportunistic infections.

8. SAE Outcome

☒ Died

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 MELANIE HILL

Signature 

Date form completed 20150213