



TasP

Antiretroviral Treatment as Prevention - ANRS 12249
(Ukuphila Kwami, ukuphila kwethu)

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Africa Centre TasP Trial

SAE-AC

Serious Adverse Event Reporting



00317306

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

20150807

i.e. Date of original Initial Notification Form

Complementary Notification Date

20150921

1. Patient details

TasP ID

48299

Name

N. Z. N.

Sex

Male

☒ Female

Date of birth

19830707

Enrolment date

20141110

2. Description of the reported SAE

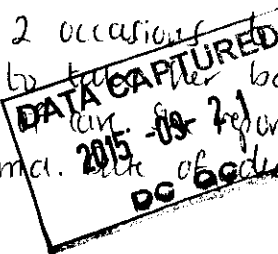
Participant with low CD4 & unsuppressed viral load on Atripla. She had deranged liver enzymes since October 2014. Latest ALP was 1647 & GG7 2390 during hospital admission. She was discharged with ultrasound booking for October 2015. 2014-2015.

Date of SAE onset

20150622

3. Complementary information

She was unable to attend trial clinic on 2 occasions to see trial clinician due to ill-health. Relatives were advised to take her back to hospital and they refused. They opted for traditional methods. She reportedly died at home due to severe diarrhoea following herbal enema. Date of death is 19/09/2015.



4. New diagnosis?

☒ Yes → Describe

No

1. Death due to herbal intoxication

2. Elevated liver enzymes (cholestatic picture)

Date of new diagnosis

20150919

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?

This includes the patient's medical history

Yes ☒ No ☐
Describe

Participant died due to severe diarrhea following herbal enema. She was still awaiting ultrasound to determine cause of elevated liver enzymes.

8. SAE Outcome

☒ Death

→ Date of death

20150919

Probable Diagnosis: Herbal intoxication

Unknown to date

Ongoing

Improved

Worsened

Recovered

→ Another complementary SAE notification form must be submitted.

→ Date of recovery

Recovered without sequelae

or

Recovered with sequelae

→ Describe

Physician reporting SAE Complementary Notification

Name GUG'ELIHE MUKHULI

Signature 

Date form completed 20150921