



TasP

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

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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



00317404

SAE No.

SAE Visit Date

20150416

Initial Notification Date

20150519

Notification time

1300

1. Patient details

TasP ID

52961

Name

Z.P.M.

Sex

Male

☒ Female

Date of birth

19830701

Enrolment date

20150410

2. Measurements

Height

157 Cms

Last known: Weight

54.1

Kgs

CD4 count

88

Viral Load

149595

DATA CAPTURED

2015-05-14

Weight Date

20150416

CD4 Date

20150416

Viral Load Date

20150416

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. Severe anaemia 20150516 20150416

2. Severe thrombo-
cytopenia 20150516 20150416

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.

Participant newly enrolled in trial. Presented to the clinic unwell, with CD4 88 and VL 149595. Had defaulted ART for unknown period of time. She was referred to hospital. At hospital she was diagnosed with severe anaemia and severe thrombocytopenia with abnormal bleeding of 8 months duration. She was transfused total 3 units of blood and 2 units platelets. She was referred to Regional hospital and was diagnosed with extrapulmonary TB and re-initiated on ART.

6. Medications

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

	Generic Name	Daily dose	Route of administration	Indication	Date started	Causality assessment	Expected reaction? (BNF/SPC)	Action taken
					Date stopped			
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?

This includes the patient's medical history

Yes ☒ No ☐

Describe

patient had longstanding history of abnormal bleeding and had defaulted ART.

8. SAE Outcome

Died

Unknown to date

Ongoing

Improved

→ A complementary SAE notification must be submitted within 8 days

☒ Recovered

→ Date of recovery

Recovered without sequelae

or

☒ Recovered with sequelae

Describe

patient now on TB treatment for extrapulmonary TB.

Physician reporting SAE

Name DR G. MUTHULU

Signature

Date form completed 20150519