



TasP

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



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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

20130917

Initial Notification Date

20130919

Notification time

0820

1. Patient details

TasP ID

30331

Name

MITHYANE ZODWA BUTHE

Sex

Male

☒ Female

Date of birth

19940117

Enrolment date

20130711

2. Measurements

Height

150 Cms

Last known: Weight

37.80 Kgs

Weight Date

20130917

CD4 count

176

CD4 Date

20

Viral Load

386

Viral Load Date

2013

DATA CAPTURED
2013 08 23
DC QC

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 CLINICAL SYMPTOMATIC ANAEMIA

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. ANAEMIA 20130917

UNKNOWN

2. TB LYMPH NODE 20130823

UNKNOWN

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.

Patient admitted to TasP trial on 11/07/2013, known HIV positive on HAART, she was started on TB treatment July 2013 and currently on active phase. During the visit on 17/09/2013, she was noticed to be weak but still able to move around unaided, severely pale Bilat. Cervical lymph node enlargement, firm, non-tender Right > left. BP - 119/69, HR - 146bpm, HS - 5.5g/dl, Not in failure. She was referred to hospital for Anaemia workup. Baseline blood shows microcytic hypochromic anaemia of HB - 7.6g/dl. Given Mefenamic acid 500mg stat and FESC4.

6. Medications

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

Generic Name	Daily dose	Route of administration	Indication	Date started	Date stopped
1. Rifampin (RHZ)	3 tabs oral	TB lymph node		201307	STILL ON
2. Pyridoxine	25mg oral	TB LN		201307	
3. Tenofovir	300mg oral	HAART			
4. Lamivudine	300mg oral	HAART			
5. Efavirenz	600mg oral	HAART			
6. Fesoy	600mg oral	Anaemia		20130913	

Causality assessment	Expected reaction? (BNF/SPC)	Action taken
Unrelated	Yes	None
Poss. related	No	Reduce
Cannot be assessed		Interrupt Stop
Unrelated	Yes	None
Poss. related	No	Reduce
Cannot be assessed		Interrupt Stop
Unrelated	Yes	None
Poss. related	No	Reduce
Cannot be assessed		Interrupt Stop
Unrelated	Yes	None
Poss. related	No	Reduce
Cannot be assessed		Interrupt Stop
Unrelated	Yes	None
Poss. related	No	Reduce
Cannot be assessed		Interrupt Stop
Unrelated	Yes	None
Poss. related	No	Reduce
Cannot be assessed		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?

Yes ☒ No ☐

This includes the patient's medical history

Describe

ANAEMIA OF CHRONIC DISEASE.

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

DR OLUWASEGUN OLUYINKA . A .

Signature

Date form completed

20130919.