



TasP

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

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Africa Centre TasP Trial

SAE-AC

Serious Adverse Event Reporting



00317308

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

20160212

i.e. Date of original Initial Notification Form

Complementary Notification Date

20160301

1. Patient details

TasP ID

19121

Name

P.P.G

Sex



Male

Female

Date of birth

19531022

Enrolment date

20130805

2. Description of the reported SAE

Participant on AZT/3TC/EFV with CD4 count 275. Reported assault on 20/11/2015. Admitted to hospital with mandibular fractures. N/A and viral load <40. with rib &

Date of SAE onset 20151220

UNIVERSITY OF KWAZULU-NATAL
AFRICA CENTRE
P.O. BOX 198, MTUBATUBA, 3935
2016-08-23

3. Complementary information

Participant discharged on 11/2/2016. Letter states that he sustained 5th, 6th & 7th rib fractures with haemothorax. The PROJECT side. Chest drain was inserted. Haemothorax recurrent. Transferred to tertiary unit. CT scan confirmed rib fractures & renal & splenic injuries. Treated conservatively. Will be followed up at local clinic.

4. New diagnosis?

Yes → Describe



No

Date of new diagnosis

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

Patient was assaulted.

8. SAE Outcome

Death → Date of death _____ Probable Diagnosis _____

Unknown to date _____

Ongoing _____

Improved _____

Worsened _____

☒ Recovered → Date of recovery 20160211

☒ Recovered without sequelae

or

Recovered with sequelae


Describe

Physician reporting SAE Complementary Notification

Name

GUGELIUS MATHIASI

Signature



Date form completed

2016 03 01