



TasP

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

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Africa Centre TasP Trial

Serious Adverse Event Reporting

SAE-AC



00093236

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

20140521

i.e. Date of original Initial Notification Form

Complementary Notification Date

20140523

1. Patient details

TasP ID

18627

Name

B.M

Sex

Male

☒ Female

Date of birth

19530527

Enrolment date

20130916

2. Description of the reported SAE

Recent discharge from hospital with diagnosis of Dementia. Review in trial clinic showed no focal neurology. Participant investigated for confusion.

Date of SAE onset

20140429

3. Complementary information

Confusion screen results showed normal B12, Folate.

Syphilis was negative. W/E showed K of 2.5

Brought to trial clinic on 21/5/2014 for review. On arrival BP 69/30 P 119. Respiratory rate 7/min, gasping & cyanosed and died whilst being resuscitated. Switched to Lamivudine/Lopinavir/ritonavir on 14/5/2014.

4. New diagnosis?

☒ Yes ☐ Describe

HYPOKALAEMIC CARDIAC ARREST

No

2° ARRHYTHMIA

Date of new diagnosis

20140521

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

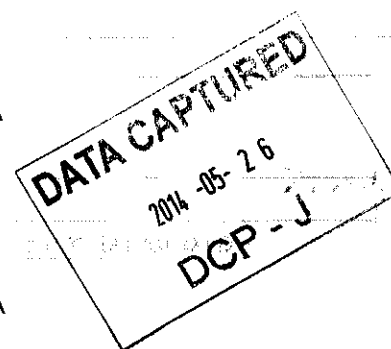
Which treatment?

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. LAMZUD AZT/3TC	800/300	OD	<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed
2. LOPINAVIR RITONAVIR	800/200	OD	<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed
3. HYDROCHLORO THIAZIDE	12.5MG SINCE 2012	OD	<input type="radio"/> Unrelated <input checked="" type="radio"/> Poss. related <input type="radio"/> Cannot be assessed
4.			<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> 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

HYPOKALAEMIC CARDIAC ARREST
2° BRADYCARDIA
HYPOKALAEMIA 2° DIURETIC THERAPY.

8. SAE Outcome

Unknown to date

Ongoing

Improved

Worsened

Recovered

Another complementary SAE notification form must be submitted within 8 days from now.

Date of recovery

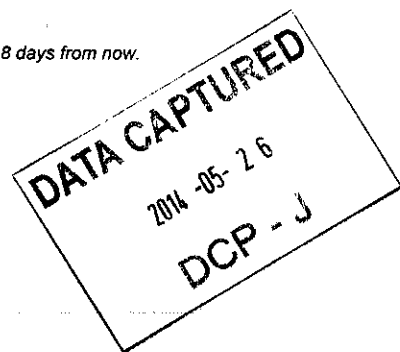
Death

☐ Recovered without sequelae

or

☐ Recovered with sequelae

Describe



Physician reporting SAE Complementary Notification

Name

COLLINS IMAJ

Signature

Kimp

Date form completed

20140523