



TasP

Antiretroviral Treatment as Prevention - ANRS 12249
Ukuphila kwami, ukuphila kwethu (my health for our health)



00317469

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

20150929

Initial Notification Date

20151023

Notification time

11 55

1. Patient details

TasP ID

33453

Name

N.M.

Sex

Male

☒ Female

Date of birth

19610331

Enrolment date

20150929

2. Measurements

Height

UUU Cms

Last known: Weight

64.0

Kgs

Weight Date

20151005

CD4 count

436

CD4 Date

20150929

Viral Load

<40

Viral Load Date

20151022

3. By which criteria is this adverse event considered to be "Serious"?

Tick all that apply

- ☐ Resulted in death → Date of death
- ☐ 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

Probable cause

DATA 2015-10-23

4. Details of SAE

Enter each adverse event (e.g. symptom, sign, syndrome or diagnosis) on a separate line

Event Name

Date investigator

Date of onset of SAE

became aware

1. Raised GGT 20151005 20150929

2.

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 transferred into TasP on 29/9/15 already on ART.

Baseline bloods showed deranged LFT's: taken 29/9/15 Bil G, ALT (61) U/L
ALP (207) U/L, GGT (838) U/L (ULN = 40).

Patient documented to abuse alcohol.

Patient called to clinic for review but is uncontactable. Referred to funding team.

6. Medications

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

	<u>Generic Name</u>	<u>Daily dose</u>	<u>Route of adminis- tration</u>	<u>Indication</u>	<u>Date started</u>	<u>Date stopped</u>	<u>Causality assessment</u>	<u>Expected reaction?</u> (BNF/SPC)	<u>Action taken</u>
1.	Atrozin from Doh clinic	T	PO	HIV	UUUUUUUUUU		Unrelated ● Poss. related Cannot be assessed	● Yes No	● None Reduce Interrupt Stop
2.	Amoxycillin	1.5g	PO	Skin infection	2015 09 29	2015 10 04	● Unrelated Poss. related Cannot be assessed	Yes ● No	● None Reduce Interrupt Stop
3.	Innospre Cream	T	TOP	Vesicles on body itching	2015 09 29	2015 10 13	● Unrelated Poss. related Cannot be assessed	Yes ● No	● None Reduce Interrupt Stop
4.							Unrelated Poss. related Cannot be assessed	Yes No	None Reduce Interrupt Stop
5.							Unrelated Poss. related Cannot be assessed	Yes No	None Reduce Interrupt Stop
6.							Unrelated Poss. related Cannot be assessed	Yes No	None Reduce 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's LFT's are deranged at baseline entry into TAPP.

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 MELANIE HUI

Signature

Date form completed 2015 10 23