



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](mailto:pharmacovigilance@anrs.fr)  
Fax: +33 153 946 002



00317459

SAE No.

SAE Visit Date

20150305

Initial Notification Date

20150422

Notification time

1730

#### 1. Patient details

TasP ID

42735

Name

M. M.

Sex

Male

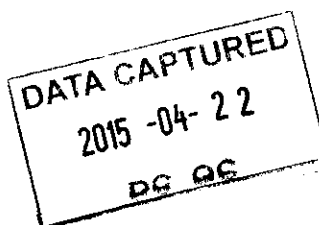
Female

Date of birth

19671227

Enrolment date

20140923



#### 2. Measurements

Height

170 cms

Last known: Weight

53.1

Kgs

Weight Date

20150305

CD4 count

190

CD4 Date

20150219

Viral Load

<40

Viral Load Date

20150219

#### 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. Renal failure 20150305 20150219

2. Gastroenteritis 20150305 20150219

3. Pulmonary TB 20150310 20150212

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.

This patient started Atripla (TDF/FTC/EFV) Oct. 2014. Ure on 19/2/15 showed creatinine 197. Patient reported diarrhoea at time Ure was taken. Refused to attend hospital + diarrhoea had stopped. Ure repeated at clinic, but creatinine worse - 314 umol/L. Was also complaining of cough, night sweats, weight loss. Sputum GeneXpert confirmed sensitive pulmonary TB. He attended Hlabisa hospital on 11/3/15 for TB treatment + management of renal failure. He was discharged on 12/3/15 with no repeat Ure. TDF was continued in hospital.

## 6. Medications

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

Generic Name	Daily dose	Route of administration	Indication	Date started	Date stopped	Causality assessment	Expected reaction? (BNF/SPC)	Action taken
1. Atoripin	1 tablet	PO	HIV	20141004		Unrelated	<input checked="" type="radio"/> Yes	<input checked="" type="radio"/> None
						<input checked="" type="radio"/> Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								Stop
2. Amoxycillin	1500mg	PO	Cough	20150212		<input checked="" type="radio"/> Unrelated	Yes	<input checked="" type="radio"/> None
				20150215		<input checked="" type="radio"/> Poss. related	<input checked="" type="radio"/> No	Reduce
						Cannot be assessed		Interrupt
								Stop
3. Vitamin B complex 1 tablet		PO	Supplement	20150211		<input checked="" type="radio"/> Unrelated	Yes	<input checked="" type="radio"/> None
				20150312		<input checked="" type="radio"/> Poss. related	<input checked="" type="radio"/> No	Reduce
						Cannot be assessed		Interrupt
								Stop
4.						Unrelated	Yes	None
						<input checked="" type="radio"/> Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								Stop
5.						Unrelated		None
						<input checked="" type="radio"/> Poss. related	Yes	Reduce
						Cannot be assessed	No	Interrupt
								Stop
6.						Unrelated		None
						<input checked="" type="radio"/> 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 This patient is immunosuppressed + at risk of TB + gastroenteritis regardless of participation in TRIP.

## 8. SAE Outcome

Died

Unknown to date

Ongoing

Improved

→ A complementary SAE notification must be submitted within 8 days

☒ Recovered

→ Date of recovery 20150312

Recovered without sequelae

or

Recovered with sequelae

Describe Creatinine level during Atoripin admission is unknown. ? whether fully corrected/normalised.

## Physician reporting SAE

Name McLAUGHLIN HILL

Signature 

Date form completed 20150422