



TasP

Antiretroviral Treatment as Prevention - ANRS 12249
Ukuphila kwami subphile number (no. health) for our health



00317466

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

20151008

Initial Notification Date

20151009

Notification time

1830

1. Patient details

TasP ID

46658

Name

D.M.

Sex

Male

☒ Female

Date of birth

19791203

Enrolment date

UUUUUUUU

2. Measurements

Height

155 Cms

Last known: Weight

43.4

Kgs

Weight Date

20151008

CD4 count

143

CD4 Date

20150521

Viral Load

641675

Viral Load Date

20150724

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

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. ?Drug Induced Liver Injury 20151008 20151001
- 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 diagnosed with TB spine - on TB Rx since 1/9/15. Is also known RVD but failing atiprive. She was reviewed in TasP clinic to be assessed for a change to 2nd line ART regimen. At the appointment she was agitated + jaundiced. Concern re. DILI 2° TB Rx + developing encephalopathy. Referred to hospital via ambulance for urgent LFT's and Confusion Screen. Told not to take TB Rx. at present.

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. RHZE	unknown	PO	TB	20150901	20151008	Unrelated	<input checked="" type="radio"/> Yes	None
						<input checked="" type="radio"/> Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								<input checked="" type="radio"/> Stop
2. Atripla	T	PO	HIV	20150225		<input checked="" type="radio"/> Unrelated	Yes	<input checked="" type="radio"/> None
						Poss. related	<input checked="" type="radio"/> No	Reduce
						Cannot be assessed		Interrupt
								Stop
3.						Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								Stop
4.						Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								Stop
5.						Unrelated		None
						Poss. related	Yes	Reduce
						Cannot be assessed	No	Interrupt
								Stop
6.						Unrelated		None
						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

Patient newly diagnosed with TB.
She is immunocompromised

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 HILL

Signature

Date form completed 20151009