



TasP

Antiretroviral Treatment as Prevention - ANRS 12249
(Ukaphila kwami ukuphila kwethu: imi Anzila for our health)



00317464

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

Initial Notification Date 2015 07 21

Notification time 10 45

1. Patient details

TasP ID

21906

Name

N.T.D.

Sex

Male

Female

Date of birth

1993 12 22

Enrolment date

2013 03 08

2. Measurements

Height

150 Cms

Last known: Weight

48.7

Kgs

Weight Date

2015 06 29

CD4 count

166

CD4 Date

2015 05 13

Viral Load

743902

Viral Load Date

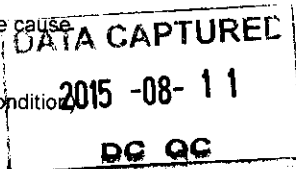
2015 05 25

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



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. Anaemia in pregnancy 20150721 20150513

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.

This patient attended TasP clinic for baseline assessment on 13/5/15. She was pregnant. Baseline Hb was 6.6. She was referred to Hlabisa hospital high-risk antenatal clinic. A repeat Hb in TasP was 5.5. TasP was informed that She was admitted due to her low Hb on 4/7/15. The gestation of her pregnancy is as yet unconfirmed. Further information to follow.

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. Atorvastatin	20mg	PO	HIV	20150615		Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								Stop
2. Ferrous Sulphate	200mg	PO	Anaemia	20150615		Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								Stop
3. Calcium Carbonate	800mg	PO	Pregnancy	20150615		Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								Stop
4. Isoniazid	300mg	PO	TB prophylaxis	20150615		Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								Stop
5. Folic acid	5mg	PO	Anaemia	20150615		Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		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

This patient joined Tasp already pregnant + anaemic.

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

20150721