



TasP

Antiretroviral Treatment as Prevention - ANRS 12249
TasP is a study to see if people who take HIV medicine can prevent HIV.



00317405

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

20150502

Initial Notification Date

20150519

Notification time

1400

1. Patient details

TasP ID

53065

Name

B.O.

Sex



Male

Female

Date of birth

29380204

Enrolment date

20150401

DATA CAPTURED

2015-05-22

DC QC

2. Measurements

Height

Cms

Last known: Weight

Kgs

Weight Date

CD4 count

401

CD4 Date

20150414

Viral Load

<40

Viral Load Date

20150414

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

Tick all that apply



Resulted in death

→ Date of death 20150508

Probable cause

Lobar Pneumonia



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

Date of onset of SAE

became aware

1.

Death due to lobar pneumonia

20150516

20150502

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.

Participant newly enrolled in trial. CD4 401, viral load <40, never been on treatment. Was due for ELISA to confirm HIV diagnosis. Known with congestive cardiac failure, on treatment. Became unwell at home, went to hospital presenting with shortness of breath & haemoptysis of streaks. He was diagnosed with lobar pneumonia on chest X-ray. Did not respond well to IV antibiotics and died on 8/5/2015

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. furosemide	40mg	oral	cardiac failure	2013	uuuu	<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input checked="" type="radio"/> Yes <input type="radio"/> No	<input checked="" type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
2. Enalapril	10mg	oral	cardiac failure	2013	uuuu	<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input checked="" type="radio"/> Yes <input type="radio"/> No	<input checked="" type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
3.						<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> interrupt <input type="radio"/> Stop
4.						<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
5.						<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
6.						<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> 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

Participant is elderly; developed severe pneumonia with poor prognosis.

8. SAE Outcome

☒ Died

Unknown to date

Ongoing

Improved

Recovered

→

→

→

or

Recovered without sequelae

Recovered with sequelae

Describe

→

Physician reporting SAE

Name DR G. MKHULISI

Signature

Date form completed 20150519