



TasP

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

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

00099539

SAE No.

SAE Visit Date

20130905

Initial Notification Date

20130911

Notification time

1530

1. Patient details

TasP ID

23157

Name

B-S

Sex

☒ Male

☐ Female

Date of birth

19531027

Enrolment date

20130517

2. Measurements

Height

158 Cms

Last known: Weight

69

Kgs

Weight Date

20130911

CD4 count

753

CD4 Date

20130905

Viral Load

450

Viral Load Date

20130709

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 CVA and left hemiplegia

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. STROKE

20130911

20130724

2.

3.

4.

5.

DATA CAPTURE

2013-09-20

DCP-F

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.

Diagnosed with HTS since 26-06-2013 and started on HCTZ and Amlodipine. Defaulted with poorly controlled HTS on every TasP visit. Patient suffered stroke on 24-07-2013 but never went to hospital. He only reported on 05-09-2013 during his monthly follow up. Patient referred to hospital for occupational therapy or physiotherapy.

## 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. Hydrochlorothiazide	12.5mg	oral	HPT	20130705		<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input checked="" type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input checked="" type="radio"/> No	<input checked="" type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
2. Amblygon comp	oral		HPT	20130705		<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input checked="" type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input checked="" 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?

Yes No

This includes the patient's medical history

Describe

stroke

## 8. SAE Outcome

☐ Died  
☐ Unknown to date  
☒ Ongoing  
☐ Improved  
☐ Recovered

A complementary SAE notification must be submitted within 8 days

Recovered → Date of recovery

Recovered without sequelae  
 or  
 Recovered with sequelae  
 Describe

## Physician reporting SAE

Name Dr. N. N. N. O. S. E. F. B. E. T. H. A. M. A.

Signature

Date form completed 20130912