South Africa - Treatment as Prevention ANRS 12249, phase 1

Africa Centre / Inserm

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Overview

Identification

ID NUMBER
ANRS12249

Version

VERSION DESCRIPTION
3.5

PRODUCTION DATE
2015-01-19

NOTES
1.0 Initial version (2 May 2014)

1.1 IndividualId in IQs dataset fixed (12 May 2014)

2.0 Initial release of version 2 (15 July 2014)

--- Generated from a new snapshot of the database, dated 22 May 2014

--- New datasets: HHIs, CHE Adverse events, CHE Action Plans, SCBs SCCs, SCIs, Specimens, Individual Consents, iDART

--- Individuals dataset: AgeGroupAtRegistration has been fixed

--- IQs dataset:

------ Health Care expenditure section has been added

------ Variables CurrentCluster, CurrentClusterType, ClusterAtRegistration, ClusterTypeAtRegistration, FormType added

------ Deprecated value fixed for variables ShouldTestWhenFeelSick to ShouldTestWhenRefused , KnowsPosMyself to KnowsPosCommunity

------ Not applicable value fixed for variables WhyNotHIVTestTodayPos to WhyNotHIVTestTodayRefused

------ Some duplicates removed

--- CBCs dataset: variables CurrentCluster, CurrentClusterType, ClusterAtRegistration, ClusterTypeAtRegistration added

--- CHEs dataset:

------ Variables CurrentCluster, CurrentClusterType, ClusterAtRegistration, ClusterTypeAtRegistration added

------ PrevTB1DateStarted, PrevTB2DateStarted and CurrTBDateStarted variables fixed

--- Lab Test Results dataset: VisitId added

--- ARTemis Patients dataset:

------ DateOfViralLoadNear6m DateOfViralLoadNear24m and DateOfViralLoadNear36m added

------ AreaOfResidenceCode recoded

3.0 Initial release of version 3 (25 September 2014)

--- Generated from a new snapshot of the database, dated 19 September 2014

--- End of data collection for phase 1 is now fixed to 31st May 2014 (included)

--- Locations dataset: ConstructionState and MappedOnDevice variables have been removed

--- Individuals dataset:

------ Trial statuses have been removed from that file and are now provided in a separate Trial Statuses dataset

------ 85 new pre-calculated variables have been added, following the TasP definitions document

--- IQs dataset: Issue of missing IQs fixed

--- Lab Tests Reults dataset: Some PIMA CD4 count documented initialy only in CHEs have been added to the dataset

3.1 Distance variables added to Locations dataset (30 Sep 2014)

3.2 Locations datatset: duplicates bug introduced in version 3.1.0 of the dataset is now fixed (7 Oct 2014)

3.3 All datasets have been regenerated (9 Oct 2014)

--- A bug with LocationId and HouseholdId has been fixed

--- Cluster dataset has been added

--- Individuals dataset:

------ BaselineClinicVisitDate and LastClinicVisitDate definition has been updated (see TasP definitions do)

------ 100 new pre-calculated variables added on retention in TasP clinics

--- Trial Statuses dataset: details of Exits have been added

--- Visits dataset: CBCcomputed, CHEcomputed, BaselineClinicVisitDate, onART, NextAppointmentDateComputed and PreviousClinicVisitDate added

--- HHIs dataset: ClusterId, CalendarRound, AssetsScore and AssetsScoreCat added

--- CBCs dataset: EarliestHIVDrugRegStartDate updated (new definition) and ARTInitiationDate removed

3.4 (23 Oct 2014)

--- Lab Test Results: duplicates (PIMA CD4 count) removed (23 Oct 2014)

--- 2 new datasets: CFUs and CFU Pill Tests

--- Shapefiles added on the repository

--- Individuals dataset

------ minor fix of variable TasPBaselineARTUse

------ 3 variables added: FirstReferralTS, EverEnteredCareAR and NewlyDiagnosedAtReferral

3.5 (19 Jan 2015)

--- New datasets:

------ SAE Initial Notifications, SAE Initial Notifications - Events details, SAE Initial Notifications - Medications, SAE Complementary Notifications & SAE Complementary Notifications - Medications

--- Individuals dataset:

------ AgeAtRegistration has been updated (now exact age and missig if year of birth is unknown)

------ New variables about age:

AgeAtReferral, AgeAtBaselineClinicVisit

------ New variables derived from IQs:

BaselineHighestEducationLevel, BaselineMaritalStatus, BaselineProfessionalStatus, BaselineEmployed & BaselineActiveStatus

------ New variables derived from iDART:

LinkedToIDART, iDARTLastEpisodeStartDateBR, iDARTLastPackageCollectionDateBR, iDARTFirstEpisodeStartDateAR,

iDARTFirstPackageCollectionDateAR, iDARTLastEpisodeStartDateBHSBT, iDARTLastPackageCollectionDateBH, iDARTFirstEpisodeStartDate,

iDARTLastEpisodeStartDate, iDARTFirstPackageCollectionDate, iDARTLastPackageCollectionDate

------ Other new variables:

NbTasPClinicVisits, InCareAtBeginning, TasPLCVDate, TasPLCVAppointmentDate, EverInCare, EverDiagnosedHIVPositive,

InCareAtEndPhase1, InTasPCareAtEndPhase1, ARTemisLastVL, ARTemisLastVLDate, TasPLastVL, TasPLastVLDate,

LastVL, LastVLDate, UndetectableVLAtEndPhase1

------ Variable updated due to changes in TasP definitions document:

SeenInTasPClinic, TasPInitiatedART, CareAtReferral, InCareAtEndPhase1, OnARTAtBeginning, OnARTAtReferral & OnARTAtEndPhase1

--- IQs dataset

------ New variables:

AgeAtIQ, NonEmploymentTypeRecoded, HighestEducationLevel2, CurrentMaritalStatus2, Employed, ProfessionalStatus, ActiveStatus

--- Visits dataset

------ Variable PreviousClinicVisitDate fixed

Overview

ABSTRACT
Background: Thirty years after the discovery of the human immunodeficiency virus (HIV), prevention is difficult to achieve and the pandemic does not show any sign of abating. Antiretroviral therapy (ART) is now rolled out at a large scale in lower-income countries. ART with fully suppressive antiretroviral (ARV) drugs combinations lowers HIV viral load (VL) in all body compartments and decreases the risk of transmission to a low level. It is thus legitimate to raise the following question: Could ART contribute to reducing transmission at individual and population level? Not only may earlier treatment reduce HIV incidence (acquisition of new cases of HIV infection through sexual or mother-to-child transmission), it may also benefit the individual. The long-term benefits of starting ART earlier would likely be of particular importance in settings where the incidence of life-threatening HIV-related diseases occurring at relatively high CD4 levels (tuberculosis, invasive bacterial diseases, and possibly malaria) is substantial, a typical situation in most sub-Saharan Africa including South Africa.

Research hypothesis: HIV testing of all adult members of a community, followed by immediate ART initiation of all, or nearly all, HIV-infected participants regardless of immunological or clinical staging will prevent onward transmission and reduce HIV incidence in this population.

Objectives: To estimate the effect of ART initiated immediately after HIV diagnosis, irrespective of CD4 count criteria, on the reduction in incidence of new HIV infections in the general population in the same setting.

Setting: The trial will be conducted in Hlabisa sub-district, Umkhanyakude district, Northern KwaZulu-Natal, South Africa. This rural setting of 1430 km2 in size has a population of approximately 220 000 Zulu-speaking people. In this sub-district, the Africa Centre for Health and Population studies, a research institute at the University of KwaZulu-Natal (<http://www.africacentre.com>) carries out socio-demographic and HIV surveillance and clinical research. The KwaZulu-Natal Department of Health and the Africa Centre established in 2004 the Hlabisa HIV Treatment and Care Programme, devolved to all 17 primary health care clinics in the sub-district. By mid-2013, over 28 000 HIV-infected people eligible for treatment had been initiated on ART; patients' treatment eligibility is determined by South African guidelines.

Design: A cluster-randomised trial with 22 (2×11) clusters will be conducted within the Hlabisa sub-district, covering a total population of approximately 22 000 inhabitants aged 16 years and above, of whom an estimated 17 600 will be HIV-negative. A full prevention and HIV testing strategy will be provided in both the intervention and control arms, consisting of the current range of community and clinic testing options plus the implementation of 6-monthly rounds of home-based HIV testing. The adult HIV-infected population residing in the intervention clusters will be offered immediate ART initiation upon HIV diagnosis whereas the HIV-infected population in the control clusters will be offered ART according to national guidelines (CD4 less than 350 cells/ml, WHO stage 3 or 4 disease or MDR/XDR TB). The protocol outlines the overall trial design, which has HIV incidence as primary outcome. The first phase of the trial (24 months) will take place in ten (2×5) clusters, with two to three rounds of home-based HIV testing and surveillance according to the trial protocol, and has as main outcome acceptability and feasibility rather than HIV incidence. If results from the first phase indicate acceptability and feasibility, the trial will be rolled-out to the other 12 clusters during the second phase. Possible amendments to the trial for phase 2 will be based on the advice from the Data Safety Monitoring Board and the Scientific Advisory Board.

Trial eligibility criteria: To be aged 16 years and above and a member of a household in the designated cluster (head of household defines membership status in KwaZulu culture).

Treatment eligibility criteria: Those already on ART from the Hlabisa HIV Treatment and Care Programme may opt to transfer their care to the trial; the few (if any) people already on ART from private/other HIV treatment providers will be encouraged to take part in the trial monitoring procedures, and be given the opportunity to change ART provider to the Hlabisa HIV Treatment and Care Programme trial.

Trial treatment: The standard first-line drug regimen will be the combination of tenofovir (TDF) + emtricitabine (FTC) + efavirenz (EFV) once daily, i.e. Atripla®. This will also be applicable to pregnant women irrespective of the trimester of pregnancy.

UNITS OF ANALYSIS
Clusters, Households, Individuals

Coverage

GEOGRAPHIC COVERAGE
Ten survey clusters located in Hlabisa sub-district, Umkhanyakude district, of northern KwaZulu-Natal, South Africa.

The Hlabisa health sub-district is a rural setting of 1 430 km2 in size, with a population of approximately 220 000 Zulu-speaking people of whom 3.3% are located in a formal urban township (KwaMsane), 19.9% in peri-urban areas and the remainder (76.8%) classified as living in a rural area. The rural population lives in scattered homesteads that are not concentrated into villages or compounds (as would be the case in many other parts of Africa).

UNIVERSE
Clusters: the trial area consists of 150 local areas (neighbourhoods). These were aggregated into 34 clusters of between one and six contiguous neighbourhoods, each cluster comprising an average of 1 000 individuals >15 years of age. Clusters were designed to encompass social networks based on earlier studies. TasP phase 1 has been implemented in 10 geographic clusters (5 control and 5 intervention).

Locations: corresponds to physical locations. There are two types of locations: homesteads and TasP clinics.

Homesteads: the population lives in scattered homesteads that are not concentrated into villages or compounds. All usable and occupied homesteads were eligible for trial participation.

Households: each homestead coul be composed of one or several households. An household remains always attached to the same homestead.

Eligible individuals : all 16 years or older and resident household members. Each individuals is attached to an household. In case of internal migration, an individual could move to another household.

TasP clinics: dedicated trial clinics implemented in each survey cluster.

Producers and Sponsors

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FUNDING

Name	Abbreviation	Role
Agence Nationale de Recherche sur le Sida et les hépatites virales	ANRS	Sponsor and funder
Deutsche Gesellschaft für Internationale Zusammenarbeit	GIZ	Funder
MERCK & Co. Inc and Gilead Sciences		Drugs supply
Wellcome Trust		Core funding of Africa Centre

Metadata Production

METADATA PRODUCED BY

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Joseph Larmarange		Ceped (UMR 196 Paris Descartes Ined IRD) / Africa Centre for Health and Population Studies	Data documentation

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3.5.0

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Sampling

Sampling Procedure

Randomisation (control clusters vs intervention clusters) was performed by the trial statisticians at the start of the trial for all clusters.

All individuals 16 years or older and resident member of a local household are eligible.

Questionnaires

No content available

Data Collection

Data Collection Dates

Start	End	Cycle
2012-03-09	2012-11-03	Calendar Round 1 - First group of clusters
2012-11-13	2013-04-19	Calendar Round 2 - First group of clusters
2013-05-02	2013-08-31	Calendar Round 3 - First group of clusters
2013-01-22	2013-07-26	Calendar Round 1 - Second group of clusters
2013-08-14	2013-03-01	Calendar Round 2 - Second group of clusters
2013-03-10	2014-05-31	TasP clinics follow-up

Time Periods

Start	End	Cycle
2012-03-09		Phase 1

Data Collection Mode

Face to face interviews

Data Collectors

Name	Abbreviation	Affiliation
Africa Centre for Health and Population Studies	AC	UKZN

Data Processing

No content available

Data Appraisal

No content available