

A cluster randomised controlled trial of an educational and organisational intervention to expand antiretroviral treatment access in public-sector primary care clinics in South Africa: the STRETCH (Streamlining Tasks and Roles to Expand Treatment and Care for HIV) trial

Submission date 26/04/2007	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 07/08/2007	Overall study status Completed	☐ Protocol
Last Edited 21/01/2013	Condition category Infections and Infestations	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

Acronym

STRETCH

Study objectives

That the decentralisation of antiretroviral treatment services from doctors at hospitals to nurses at clinics, supported by appropriate training and supervision, expands treatment access, reducing mortality among enrolled patients waiting for HAART (Highly Active AntiRetroviral Treatment), without compromising HAART treatment outcomes.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Ethics Committee of the Faculty of Health Sciences, University of the Free State (South Africa) (ref: ETOVS NR 75/07)
2. Ethics Committee of the Faculty of Health Sciences, University of Cape Town (South Africa), approval pending as of 16/07/2007

Study design

Pragmatic, two-arm, cluster randomised controlled trial.

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

HIV/ AIDS

Interventions

Complex health systems intervention comprising:

1. Clinical algorithm to triage AntiRetroViral (ARV) patients for nurse- or doctor-managed care
2. Educational outreach training to nurses
3. Expanded prescribing provisions to permit trained nurse practitioners to prescribe ARVs
4. Re-defining roles of clinical staff:
 - 4.1. Generalist nurses: pre-ARV HIV care
 - 4.2. ARV nurses: monitoring of stable ARV patients, ARV initiation in selected adults
 - 4.3. ARV doctors: review problem cases
5. Systems toolkit: a guideline for managers on how to implement STRETCH
6. Provincial STRETCH co-ordinators
7. STRETCH facility support teams - facilitate changes and provide support

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

antiretroviral treatment (HAART)

Primary outcome(s)

The following will be analysed at 1 year (interim analysis) and 2 years (final analysis):

Cohort 1: Survival

Cohort 2: Viral load suppression rates

Key secondary outcome(s)

The following will be measured at 2 years (or 1 year if the trial should be discontinued):

Cohort 1:

1. Viral load suppression rates
2. Duration between enrolment and starting HAART
3. Proportion of patients with CD4 count ≤ 350 who start HAART during the study period
4. Median baseline CD4 count of patients starting HAART
5. Tuberculosis (TB) case detection
6. Screening for TB (sputum tests)
7. Cotrimoxazole prophylaxis provision
8. Changes in CD4 and weight, hospital admissions
9. Number of nurse and doctor visits

Cohort 2:

1. Survival
2. Programme retention (the proportion of patients remaining alive and in care)
3. Duration of viraemia prior to switch to second-line treatment
4. TB case detection
5. Screening for TB (sputum tests)
6. Cotrimoxazole prophylaxis provision
7. Changes in CD4 and weight
8. Hospital admissions
9. Number of nurse and doctor visits

Completion date

30/06/2009

Eligibility

Key inclusion criteria

Clinics: All 31 public sector clinics currently offering antiretroviral treatment in the Free State province, South Africa.

Patients:

Cohort 1: All patients enrolled at the 31 facilities with a CD4 count of 350 cells/ul or less not yet on HAART.

Cohort 2: All patients enrolled at the 31 facilities already on HAART for 6 months or longer, and alive and in care at the start of the trial.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

Clinics: None

Patients: Patients younger than 18 years

Date of first enrolment

01/07/2007

Date of final enrolment

30/06/2009

Locations**Countries of recruitment**

South Africa

Study participating centre

Knowledge Translation Unit

Cape Town

South Africa

7937

Sponsor information**Organisation**

Development Cooperation Ireland (South Africa)

Funder(s)**Funder type**

Government

Funder Name

Canadian International Development Agency (02/2006) (Canada)

Funder Name

Irish Aid (Ireland)

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	08/09/2012		Yes	No
Other publications	process evaluation	16/07/2012		Yes	No