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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

Registration date
07/08/2007

Overall study status
Completed

Last Edited
21/01/2013

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Lara Fairall

Contact details
Knowledge Translation Unit
University of Cape Town Lung Institute
PO Box 34560
Groote Schuur
Cape Town
South Africa
7937
+27 21 406 6979
lfairall@uctgsh1.uct.ac.za

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