ISRCTN48682427 https://doi.org/10.1186/ISRCTN48682427

Directly Observed antiretroviral Therapy for people living with Human Immunodeficiency Virus (HIV) and Acquired ImmunDeficiency Syndrome (AIDS): a randomised controlled trial

Submission date
01/01/2004

Recruitment status
No longer recruiting

Registration date
02/03/2004

Overall study status
Completed

Last Edited
06/11/2009

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Acronym
DOT-AIDS

Study objectives
Not provided at time of registration

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
HIV/AIDS

Interventions
Intervention group:
Twice-weekly home visits performed by community-peer educators over a two month period. Thereafter, patients were visited once a week for four months. The purpose of the peer educators was to assist the patients in taking medication and provide information and support related to adherence, the importance of following physician recommendations and information related to healthy behaviour (e.g. safe sex, supportive measures related to stigma, and adherence strategies).

Control group:
Usual care provided by the outpatient clinics.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Adherence to highly active antiretroviral therapy (HAART) at the end of the study (6 months)
2. Diseases progression
3. Occurence of AIDS-related disease/opportunistic infections

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/2004

Completion date
31/12/2004

Eligibility

Key inclusion criteria
1. HIV-1 infected individuals
2. 18 years old or older
3. Starting antiretroviral therapy in three AIDS clinics in Porto Alegre (Brazil)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
Not provided at time of registration

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/01/2004

Date of final enrolment
31/12/2004

Locations

Countries of recruitment
Brazil

Study participating centre
Rua Landel de Moura, 1369
Porto Alegre
Brazil
91920-150

Sponsor information

Organisation
Ministry of Health (Brazil)

Sponsor details
Ministério da Saúde
Secretaria de Políticas de Saúde
Coordenação Nacional de DST e Aids
Grupo Matricial de Pesquisa e Vacinas
W3 Norte - SEPN 511 - Bloco C
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Sponsor type
Government

Website
http://portal.saude.gov.br/portal/saude/default.cfm

ROR
https://ror.org/02y7p0749

Funder(s)

Funder type
Government

Funder Name
Ministry of Health (Brazil)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration