

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	<input type="checkbox"/> Prospectively registered
Registration date 02/03/2004	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 06/11/2009	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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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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Brazil

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aids@aids.gov.br

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