# A Phase III randomised, double-blind, multicentre study to evaluate the safety and efficacy of 1592U89 (abacavir) in human immunodeficiency virus 1-infected patients with aquired immune deficiency syndrome dementia complex

| Submission date   | Recruitment status          | Prospectively registered       |  |  |
|-------------------|-----------------------------|--------------------------------|--|--|
| 21/03/2006        | No longer recruiting        | ☐ Protocol                     |  |  |
| Registration date | Overall study status        | Statistical analysis plan      |  |  |
| 19/06/2006        | Completed                   | [X] Results                    |  |  |
| Last Edited       | Condition category          | [] Individual participant data |  |  |
| 27/09/2012        | Infections and Infestations |                                |  |  |

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

**Prof Bruce Brew** 

#### Contact details

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# Additional identifiers

ClinicalTrials.gov (NCT)

#### Protocol serial number

**CNAB 3001** 

# Study information

#### Scientific Title

#### Study objectives

The addition of abacavir to an antiretroviral regimen in patients with aquired immune deficiency syndrome (AIDS) dementia will lead to improved neuropsychological performance

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

This study was reviewed and approved by Riverside Ethics Committee, Chelsea and Westminster Hospital on 05/12/1996, reference number: 1163

#### Study design

Randomised, double-blind, placebo-controlled study

#### Primary study design

Interventional

#### Study type(s)

**Treatment** 

# Health condition(s) or problem(s) studied

HIV-1 infection with AIDS dementia

#### **Interventions**

Subjects were pre-stratified into group A or B depending on whether their respective existing therapy contained zidovudine (ZDV) or not.

Subjects receiving stavudine (d4T) were stratified into group B. Study participants were randomized within each stratum to receive either 600 mg of abacavir (ABC) or matched placebo every twelve hours in addition to their current antiretroviral therapy for the first 12 weeks of the study.

At the end of the randomized phase or at the time of AIDS dementia complex (ADC) progression, or severe antiretroviral drug toxicity not related to ABC, there was the option of continuing the study further for 40 weeks receiving open label ABC.

#### Intervention Type

Drug

#### Phase

Phase III

#### Drug/device/biological/vaccine name(s)

1592U89 (Abacavir)

## Primary outcome(s)

Improvement in neuropsychological performance.

## Key secondary outcome(s))

Reduction in cerebrospinal fluid HIV viral load.

#### Completion date

08/01/1998

# **Eligibility**

# Key inclusion criteria

Confirmed human immunodeficiency virus-1 (HIV-1) seropositive male or female subjects, aged 18 to 65 years, diagnosed with stage 1 or 2 (mild to moderate) AIDS dementia complex and stable on current antiretroviral therapy for a minimum of eight weeks prior to study entry were enrolled. Subjects were impaired by at least 1.5 standard deviations (SDs) below normal in at least two neuropsychological domains from the neuropsychological test battery

### Participant type(s)

Patient

#### Healthy volunteers allowed

No

## Age group

Adult

# Lower age limit

18 years

#### Sex

All

# Key exclusion criteria

Subjects with evidence of confounding neurological disease or presenting with other central nervous system (CNS) opportunistic infections or neoplasms were excluded

#### Date of first enrolment

03/09/1996

#### Date of final enrolment

08/01/1998

# Locations

#### Countries of recruitment

**United Kingdom** 

Australia

Canada

United States of America

Study participating centre
Department of Neurology
Sydney
Australia
2010

# Sponsor information

# Organisation

GlaxoSmithKline (UK)

#### **ROR**

https://ror.org/01xsqw823

# Funder(s)

# Funder type

Industry

#### **Funder Name**

GlaxoSmithKline

#### Alternative Name(s)

GlaxoSmithKline plc., GSK plc., GlaxoSmithKline plc, GSK

# **Funding Body Type**

Government organisation

# **Funding Body Subtype**

For-profit companies (industry)

#### Location

**United Kingdom** 

# Funder Name

NIH grants: NS44807 (McArthur JC) and NS094659 (McArthur JC)

# **Results and Publications**

Individual participant data (IPD) sharing plan

# IPD sharing plan summary

# **Study outputs**

| Output type     | Details       | Date created | Date added | Peer reviewed? | Patient-facing? |
|-----------------|---------------|--------------|------------|----------------|-----------------|
| Results article | results       | 13/04/2001   |            | Yes            | No              |
| Study website   | Study website | 11/11/2025   | 11/11/2025 | No             | Yes             |