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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
21/03/2006

Registration date
19/06/2006

Last Edited
27/09/2012

Recruitment status
No longer recruiting

Overall study status
Completed

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

Study website
http://ctr.gsk.co.uk/summary/abacavir/III_CNAB3001.pdf

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00002163

Secondary identifying numbers
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

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-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 measure
Improvement in neuropsychological performance.

Secondary outcome measures
Reduction in cerebrospinal fluid HIV viral load.

Overall study start date
03/09/1996

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
90

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
Australia

Canada

United Kingdom

United States of America

Study participating centre
Department of Neurology
Sydney
Australia
2010

Sponsor information

Organisation
GlaxoSmithKline (UK)

Sponsor details
Stockley Park West
Uxbridge
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Sponsor type
Industry

Website
http://www.gsk.com

ROR
https://ror.org/01xsqw823

Funder(s)

Funder type
Industry

Funder Name
GlaxoSmithKline

Alternative Name(s)
GlaxoSmithKline plc., GSK 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

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

Study outputs

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