ISRCTN58811572 https://doi.org/10.1186/ISRCTN58811572

Randomised, double-blind, placebo controlled, study to evaluate the safety and efficacy of acetyl L-carnitine (ALCAR), in combination with antiretroviral therapy, for prevention of distal symmetric polyneuropathy (DSP) and lipid abnormalities in treatment of human immunodeficiency virus (HIV)

Submission date
30/09/2005

Recruitment status
No longer recruiting

Registration date
30/09/2005

Overall study status
Completed

Last Edited
18/07/2016

Condition category
Nervous System Diseases

[ ] 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

Protocol serial number
N0256146998

Study information

Scientific Title
Randomised, double-blind, placebo controlled, study to evaluate the safety and efficacy of acetyl L-carnitine (ALCAR), in combination with antiretroviral therapy, for prevention of distal symmetric polyneuropathy (DSP) and lipid abnormalities in treatment of human immunodeficiency virus (HIV)

Study objectives
Does the use of acetyl L-carnitine (ALCAR) prevent the occurrence of distal symmetric polyneuropathy (DSP) (a side effect of antiretroviral therapy)?

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

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Distal symmetric polyneuropathy (DSP)

Interventions
Randomised controlled trial

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Acetyl L-carnitine

Primary outcome(s)

Primary endpoint: the change in baseline in total area of PGP (protein gene product) immunostaining on the epidermis at 48 weeks

Key secondary outcome(s))
Not provided at time of registration

Completion date
31/12/2003

Eligibility

Key inclusion criteria
40 patients

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/11/2002

Date of final enrolment
31/12/2003

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Department of Infection & Immunity
London
United Kingdom
NW3 2QG

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Government

Funder Name
The Royal Free Hampstead NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration