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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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/11/2002

Completion date
31/12/2003

Eligibility

Key inclusion criteria
40 patients

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
40

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
England

United Kingdom

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

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
The Royal Free Hampstead NHS Trust (UK)

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