

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	☐ Prospectively registered
Registration date 30/09/2005	Overall study status Completed	☐ Protocol
Last Edited 18/07/2016	Condition category Nervous System Diseases	☐ 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

Contact name

Dr Margaret A Johnson

Contact details

Department of Infection & Immunity
Royal Free Hampstead NHS Trust
Pond Street
Hampstead
London
United Kingdom
NW3 2QG
+44 (0)20 7794 0500 ext 3082
Sally.Allen@royalfree.nhs.uk

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

Primary study design

Interventional

Study design

Randomised controlled trial

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