ISRCTN87024790 https://doi.org/10.1186/ISRCTN87024790

High dose Coenzyme Q10 and vitamin E therapy in Friedreich's ataxia

Submission date	Recruitment status	[_] Prospectively registered
10/01/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
01/02/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
27/09/2011	Nervous System Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Anthony Schapira

Contact details
Department of Clinical Neurosciences
Royal Free & University College Medical School
Rowland Hill Street
London
United Kingdom
NW3 2PF

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
FAQES4

Study information

Scientific Title

Acronym
QES4

Study objectives
High doses of coenzyme Q10 and vitamin E given daily over two years will modifiy disease progression in patients with genetically proven Friedreich's ataxia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Royal Free Local Research Ethics Committee (UK), Ref 5405, approved 16/05/2001.

Study design
Randomised double blind controlled trial, involving 2 arms; high doses of coenzyme Q10 / vitamin E; low doses of coenzyme Q10 / vitamin E

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Friedreich's ataxia

Interventions
High doses of coenzyme Q10 / vitamin E vs Low doses of coenzyme Q10 / vitamin E

Intervention Type
Supplement

Phase
Not Specified

Drug/device/biological/vaccine name(s)
coenzyme Q10, vitamin E

Primary outcome measure

Significant improvement in the rate of change in the International Cooperative Ataxia Ratings Scale (ICARS) scores over two years of the trial in the high dose versus the low dose treatment groups

Secondary outcome measures
1. Rate of change in the kinetic, posture and gait, speech, ocular subscores of the ICARS

2. Rate of change in the following:
a. speech tests (PaTa repetition, speed of reading)
b. upper limb coordination tests (hand clicker, modified peg board, hand target, BRAIN kinesia)
c. lower limb coordination tests (foot target, box)
d. cardiac tests (IVS, PWd and fraction shortening)
e. activities of daily living scale

Overall study start date
01/09/2001

Completion date
01/05/2004

Eligibility

Key inclusion criteria
1. Homozygous for the GAA expansion in the FRDA gene characteristic of the disease
2. Able and willing to attend the assessments over the trial period
3. Over 10 years of age at the start of the trial

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
50

Key exclusion criteria
1. Planned surgery during the trial period
2. An ICARS score greater than 80% of the maximum
3. Taking coenzyme Q10, vitamin E or other antioxidants
4. Planned pregnancy

Date of first enrolment
01/09/2001

Date of final enrolment
01/05/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Clinical Neurosciences
London
United Kingdom
NW3 2PF

Sponsor information

Organisation
Royal Free Hospital Trust (UK)

Sponsor details
Royal Free Hospital Trust
Pond Street
London
England
United Kingdom
NW3 2PF

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04rtdp853

Funder(s)

Funder type
Charity

Funder Name
Ataxia UK (UK)

Alternative Name(s)
Ataxia

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

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	01/12/2008		Yes	No