

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

<b>Submission date</b> 10/01/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 01/02/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 27/09/2011	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## 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 modify 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?
<a href="#">Results article</a>	results	01/12/2008		Yes	No