

Determination of effects of Coenzyme Q10 or ubiquinol in human gene expression and related physiological readouts

Submission date 18/06/2012	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 29/06/2012	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 20/10/2017	Condition category Other	☐ Individual participant data

Plain English summary of protocol

Background and study aims

Studies on cells and mice indicate a role for Coenzyme Q10 in gene expression (the process by which genetic instructions are used to make proteins). The reduced form of Coenzyme Q10, ubiquinol, also acts as an antioxidant and regenerator of other antioxidants such as vitamin E. The aim of this study is to determine the effects of ubiquinol on gene expression.

Who can participate?

Healthy male volunteers aged between 21 and 48

What does the study involve?

All participants take ubiquinol daily in the form of three soft gel capsules with each meal for 14 days. Blood samples are collected after two weeks of supplementation and the effects of ubiquinol on gene expression are assessed.

What are the possible benefits and risks of participating?

Participants may benefit from an improvement in their antioxidative potential and fat metabolism. No side effects are expected.

Where is the study run from?

University of Kiel (Germany)

When is the study starting and how long is it expected to run for?

January 2009 to March 2009

Who is funding the study?

Kaneka Corporation (Japan)

Who is the main contact?

Prof. Dr Frank Döring

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

A 121/07

Study information

Scientific Title

Ubiquinol supplementation in humans: a proof of principle study

Study objectives

Coenzyme Q10 alters gene expression of inflammatory genes via DNA methylation.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics committee of the Medical Faculty of Kiel University, 13/03/2007, ref: A 121/07

Primary study design

Interventional

Study design

Proof of principle study

Study type(s)

Other

Health condition(s) or problem(s) studied

Ubiquinol supplementation study

Interventions

Ubiquinol supplementation, all participants got the same treatment: 150 mg Q10H2 daily in the form of three softgel capsules (50 mg) with each principal meal for 14 days.

Intervention Type

Supplement

Primary outcome(s)

Total blood collected after two weeks of supplementation

1. CoQ10 Analysis
2. Routine blood parameters

Key secondary outcome(s)

1. DNA methylation patterns
2. mRNA expression in monocytes

Completion date

31/03/2009

Eligibility

Key inclusion criteria

1. Age >17 years
2. Gender: Male
3. No history of gastrointestinal, hepatic, cardiovascular or renal diseases
4. A habit of non- or occasional smoking and maintenance of usual nutrition habits

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Sex

Male

Key exclusion criteria

1. Age <17 years
2. Gender: Female
3. History of gastrointestinal, hepatic, cardiovascular or renal diseases, smoking, eating disorders

Date of first enrolment

01/01/2009

Date of final enrolment

31/03/2009

Locations

Countries of recruitment

Germany

Study participating centre

University of Kiel

Kiel

Germany

24118

Sponsor information

Organisation

Kaneka Corporation (Japan)

ROR

<https://ror.org/038ckz871>

Funder(s)

Funder type

Industry

Funder Name

Kaneka Corporation (Japan)

Results and Publications

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	01/01/2011		Yes	No
Results article	results	21/07/2011		Yes	No

Results article	results	01/10/2012	Yes	No
Results article	results	04/07/2014	Yes	No