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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 [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 29/06/2012	**Overall study status** Completed	
Last Edited 20/10/2017	**Condition category** Other	

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
fdoering@molprev.uni-kiel.de

Contact information

Type(s)
Scientific

Contact name
Prof Frank Döring

Contact details
University of Kiel
Department of Moleccular Prevention
Heinrich-Hecht-Platz 10
Kiel
Germany
24118
+49 (0)431 8805657
fdoering@molprev.uni-kiel.de

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Proof of principle study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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 measure
Total blood collected after two weeks of supplementation
1. CoQ10 Analysis
2. Routine blood parameters

Secondary outcome measures
1. DNA methylation patterns
2. mRNA expression in monocytes

Overall study start date
01/01/2009

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

Age group

Adult

Sex
Male

Target number of participants
53

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)

Sponsor details
c/o Kazunori Hosoe
3-2-4, Nakanoshima, Kita-ku
Osaka
Japan
530-8288

Sponsor type
Industry

ROR
https://ror.org/038ckz871

Funder(s)

Funder type
Industry

Funder Name
Kaneka Corporation (Japan)

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	01/01/2011		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