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The potential influence of chicken egg consumption on humans

Submission date	Recruitment status	[_] Prospectively registered
29/03/2022	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
15/04/2022	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
18/04/2023	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Background and study aims
Recent evidence has suggested the presence of extracellular vesicles (EVs) or exosome-like particles in food products such as milk and apple juice. These EVs contain miRNA as their cargo. miRNAs can silence gene expression by repression or degradation of mRNA. Hence, these foods containing miRNA in EVs may have important implications for human health. This study aims to investigate the presence of EVs in chicken eggs and whether egg consumption alters miRNA levels in human blood. The study also aims to highlight the potential of these EV-miRNA in influencing gene expression in humans.

Who can participate?
Healthy adults aged 24-36 years who are not pregnant or allergic to chicken eggs

What does the study involve?
Participants are randomly allocated to consume two, three or four eggs at three visits. There is a 1-week break between the visits. Blood and urine samples are collected before and after the consumption of eggs at different time intervals (i.e. 3, 4.5, 9, 12 and 24 hours).

What are the possible benefits and risks of participating?
There is no direct benefit to the participants. Blood sampling may cause anxiety in some participants. Therefore, experts who are trained and experienced in blood collection assist in sampling blood.

Where is the study run from?
University of Nebraska (USA)

When is the study starting and how long is it expected to run for?
October 2014 to October 2017

Who is funding the study?
1. National Institute of Food and Agriculture (NIFA) (USA)
2. National Institutes of Health (NIH) (USA)
3. Gerber Foundation (USA)

4. The Egg Nutrition Centre (USA)
5. University of Nebraska (USA)

Who is the main contact?
Dr Javaria Munir
jmunir2@unl.edu

Contact information

Type(s)
Scientific

Contact name
Dr Javaria Munir

ORCID ID
http://orcid.org/0000-0002-5981-0329

Contact details
Department of Nutrition and Health Sciences
University of Nebraska-Lincoln
316 Leverton Hall
Lincoln
United States of America
68583
+1 (0)4022193670
jmunir2@unl.edu

Type(s)
Scientific

Contact name
Prof Janos Zempleni

ORCID ID
http://orcid.org/0000-0001-5492-4661

Contact details
Department of Nutrition and Health Sciences
University of Nebraska-Lincoln
316 Leverton Hall
Lincoln
United States of America
68583
+1 (0)402 472 3270
jzempleni2@unl.edu

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Presence of extracellular vesicles and their miRNA cargo in chicken eggs and their potential to alter gene expression in non-avian species

Study objectives
Chicken egg contains exosomal miRNA and egg consumption potentially modulates gene expression in humans.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/10/2014, University of Nebraska Institutional Review Board, Lincoln (University of Nebraska-Lincoln, Office of Research and Economic Development, 2200 Vine Street, 275 Prem S. Paul Research Center at Whittier School, Lincoln, NE 68583-0863, USA; +1 (0)402 472 4491, +1 (0) 402 472 8196; squinn@unl.edu, rwenzl2@unl.edu), ref: IRB 14585

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
Patient information sheets were collected as hard copies and are not available online.

Health condition(s) or problem(s) studied
Change in expression of miRNA/mRNA in humans after consumption of egg EVs

Interventions
In the first feeding study, five men and two women (ages 24-36 years) are randomly shuffled and assigned into groups: a group fed with two eggs, a group fed with three eggs and a group fed with four eggs. The second dose and third doses are administered using the same strategy as the first dose with a 1-week wash-out period between doses. Eggs are consumed as a single dose in 10 minutes. Participants are requested to not consume any poultry product before 24 hours. Blood is collected before egg consumption and after egg consumption (i.e. after 3, 4.5, 9, 12 and 24 hours). miRNA analysis is performed. Moreover, urine samples are collected before egg consumption and after every dose, followed by miRNA analysis.

In the second feeding study, five men (ages 26-35 years) are given a dose of four hard-boiled eggs. Blood plasma and peripheral blood mononuclear cells (PBMCs) are collected from the participants. miRNA analysis is performed from blood and PBMCs.

Intervention Type
Other

Primary outcome measure
miRNA expression in blood plasma evaluated using quantitative real-time polymerase chain reaction (RT-qPCR) before and after consumption of hard-boiled eggs using 3, 4.5, 9, 12, 24 hours as timepoints

Secondary outcome measures
miRNA expression in peripheral blood mononuclear cells (PBMCs) evaluated using RT-qPCR before and after consumption of hard-boiled eggs using 3, 4.5, 9, 12, 24 hours as timepoints

Overall study start date
08/10/2013

Completion date
17/10/2017

Eligibility

Key inclusion criteria
Healthy adults:
1. Ten men (aged 24-36 years)
2. Two women (aged 24-36 years)

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
12

Total final enrolment
12

Key exclusion criteria
1. Pregnant
2. Smoking
3. Allergic to eggs

Date of first enrolment
06/10/2014

Date of final enrolment
11/08/2016

Locations

Countries of recruitment
United States of America

Study participating centre
University of Nebraska-Lincoln
Department of Nutrition and Health Sciences
316C Leverton Hall
Lincoln
United States of America
68583

Sponsor information

Organisation
National Institute of Food and Agriculture

Sponsor details
805 Pennsylvania Avenue
Kansas City
United States of America
64105
+1 (0)202 401 4986
awards@nifa.usda.gov

Sponsor type
Government

Website
https://nifa.usda.gov/visit-nifa

ROR
https://ror.org/05qx3fv49

Funder(s)

Funder type
Government

Funder Name
The Egg Nutrition Centre

Funder Name
National Institute of Food and Agriculture

Alternative Name(s)
USDA National Institute of Food and Agriculture, USDA's National Institute of Food and Agriculture, National Institute for Food and Agriculture of the United States Department of Agriculture, National Institute of Food and Agriculture at USDA, National Institute of Food and Agriculture (USDA), National Institute of Food & Agriculture, USDA/National Institute of Food and Agriculture, U.S. Department of Agriculture, National Institute of Food and Agriculture, Cooperative State Research, Education, and Extension Service, NIFA, USDA - NIFA, USDA NIFA, NIFA USDA, USDA/NIFA, CSREES

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United States of America

Funder Name
National Institutes of Health

Alternative Name(s)
Institutos Nacionales de la Salud, US National Institutes of Health, NIH

Funding Body Type
Government organisation

Funding Body Subtype

National government

Location
United States of America

Funder Name
Gerber Foundation

Alternative Name(s)
The Gerber Foundation, GerberFdnWMI, The Gerber Companies Foundation, GF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United States of America

Funder Name
University of Nebraska-Lincoln

Alternative Name(s)
University of Nebraska, Lincoln, University of Nebraska, Nebraska, Universitas Nebraskensis, UNL, NU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United States of America

Results and Publications

Publication and dissemination plan
Publication in a high-impact factor journal in the field of nutrition.

Intention to publish date
30/07/2022

Individual participant data (IPD) sharing plan

No individual data will be shared; data will be reported in aggregated form. The participant-level data were collected as hard copies and stored in the designated space in the university. The study including all data analysis was completed in 2017 and the patients' data were kept safely for 3 years after the completion of the study i.e. until 2020. After the specified period, the participant-level data were destroyed.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results of second feeding study	14/04/2023	18/04/2023	Yes	No