ISRCTN58438021 https://doi.org/10.1186/ISRCTN58438021

Characterisation of chewed/sucked and expectorated raw almonds

Submission date	Recruitment status
05/11/2013	No longer recruiting
Registration date	**Overall study status**
13/11/2013	Completed
Last Edited	**Condition category**
09/01/2015	Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
We have developed a theoretical model for studying the release of nutrients from plant foods, specifically lipid (fat) from almond cells. The model calculates the amount of lipid released from the ruptured cells of almond cubes of specific size. The model shows that as the cubes get smaller, the number of ruptured cells, and therefore the amount of lipid released per gram of almond, increases. We require information on the number of particles of each size for chewed almond in order to calculate the amount of lipid released in a more realistic situation. The main aim of the study is to measure the size of almond particles that have been chewed sufficiently to be swallowed.

Who can participate?
We are looking for adults who have healthy teeth and are not allergic to almonds or associated allergens to participate in this study.

What does the study involve?
Once we have checked the eligibility and participants have given consent, we will ask them to attend a chewing session. Participants may be requested to attend a maximum of five additional sessions. During each session (about 1.5-2 hours) they will be given ten samples of almonds (raw whole almonds or cooked whole almonds, with the skins). They will be asked to chew and swallow the first two samples as normal, while we count the number of chews and record the time from their first chew to the swallowing. For the remaining eight samples, they will be asked to chew normally but then spit out the contents of their mouth rather than swallowing them. Between each sample they will be given some water to rinse their mouth which we will also collect. In addition, some participants will be asked to chew and spit a small handful of each type of almond, which will be used for the simulated digestion. This may be at the same time or separate from the main sessions. Finally at the end of one session, we will ask you to suck some almond cubes for 30 seconds before spitting them out.

What are the possible benefits and risks of participating?
We dont anticipate any direct benefits to participants from taking part, but it will help us understand the digestion and absorption of fat from plant foods. However, anthropometric measurements (height, weight and BMI) will be available to all participants at the screening

stage. Results will be available to all participants. We believe the risks to participants are minimal as the study involves everyday activities. Our main concern is that individuals who are allergic to nuts do not take part.

Where is the study run from?
Kings College London, UK.

When is the study starting and how long is it expected to run for?
The study started in April 2011 and will run until May 2014.

Who is funding the study?
The Biotechnology and Biological Sciences Research Council (BBSRC), UK.

Who is the main contact?
Terri Grassby terri.grassby@kcl.ac.uk
Myriam Grundy myriam.grundy@kcl.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Peter Ellis

Contact details
King's College London
Biopolymers Group
Department of Biochemistry
Diabetes & Nutritional Sciences Division
Franklin-Wilkins Building
London
United Kingdom
SE1 9NH

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

The role of plant cell walls in regulating starch and lipid bioaccessibility from plant foods: in silico, in vivo and in vitro studies

Study objectives
The particles of almond following mastication will have different sizes, and their proportion will vary between size ranges.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North London REC 1, REC reference 10/H0717/96

Study design
Randomised cross-over design trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Other

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

Health condition(s) or problem(s) studied
Digestion and nutrient bioaccessibility

Interventions
Volunteers are randomly allocated to treatments using an electronic randomisation program

1. Mastication and expectoration of whole raw and roasted almonds.
2. Mastication and expectoration of muffins containing almond flour or almond particles of 2 mm.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure

Measure the size of almond particles that have been chewed sufficiently to be swallowed. Mechanical sieving and laser diffraction are used to measure particle size distribution of the expectorated and digested almonds.

Secondary outcome measures
1. Find shape parameters (numerical values) that describe the general particle shape to allow the theoretical model to predict lipid release from intact cells: examined by microscopy (light, scanning electron and transmission)
2. Measure any changes in lipid content and cell-wall polysaccharide composition due to chewing. Quantifying the amount of lipid lost using the Soxhlet method and cell wall changes by gas chromatography.
3. Determine whether cooking almonds affects the release of lipid from the chewed almonds: examined by microscopy (light, scanning electron and transmission)
4. Determine whether lipid is removed from ruptured cells only when in the presence of saliva: examined by microscopy (light, scanning electron and transmission)
5. Determine the effects of chewing on lipid release and cell-wall structure during simulated gastric (stomach) digestion. Quantifying the amount of lipid lost using the Soxhlet method and cell wall changes by gas chromatography.
6. Evaluate how almond incorporated into a complex food structure (muffin) behaves following chewing and simulated digestion. Quantifying the amount of lipid lost using the Soxhlet method and cell wall changes by gas chromatography.

Time points:
1. Baseline (analysis of raw and roasted almonds, and muffins)
2. After mastication
3. During/after gastric digestion (various time points depending on the test food, i.e. almond vs muffin)
4. After duodenal digestion

Chewed almond and muffins are loaded into an in vitro digestion model (Dynamic Gastric Model at the Institute of Food Research in Norwich)

Overall study start date
15/04/2011

Completion date
15/05/2014

Eligibility

Key inclusion criteria
1. Be generally healthy
2. Healthy dentition
3. Be at least 18 years old
4. Have eaten almonds with no adverse effects

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
15

Key exclusion criteria
You must not:
1. Be allergic to nuts of any kind
2. Be allergic to celery, pears, apples, cherries, peaches or parsley
3. Have any teeth missing (apart from unerupted wisdom teeth)
4. Have bleeding gums
5. Had dental treatment (other than checkups) in the last 3 months
6. Be currently suffering from any infectious disease that may be passed on via saliva e.g. Glandular fever, flu
7. Be allergic to wheat, gluten or milk, if chewing the almond muffin meals

Date of first enrolment
15/04/2011

Date of final enrolment
15/05/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
King's College London
London
United Kingdom
SE1 9NH

Sponsor information

Organisation
King's College London (UK)

Sponsor details

c/o Keith Brennan
Room 1.8
Hodgkin Building
Guy's Campus
London
England
United Kingdom
SE1 4UL

Sponsor type
University/education

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Research council

Funder Name
Biotechnology and Biological Sciences Research Council (BBSRC) (UK), reference BB/H004866/1

Alternative Name(s)
UKRI - Biotechnology And Biological Sciences Research Council, BBSRC UK, BBSRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

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	01/01/2015		Yes	No