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Prevention of oral cancer by tea

Submission date	Recruitment status	[_] Prospectively registered
07/12/2011	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
06/01/2012	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
21/05/2015	Cancer	

Plain English summary of protocol

Background and study aims
Many laboratory studies in cells or on animals show that tea consumption protects against cancer at various sites, but results from studies in humans have been less clear. Whereas some studies show a benefit of tea in preventing certain cancers, other studies have shown no effect of tea drinking on cancer risk. A few years ago, a study of tea drinking among mostly smokers demonstrated that tea drinking resulted in a reduced risk of oral (mouth) cancer. These findings are similar to the animal studies, and support the idea that tea is protective against cancer. While the mechanisms by which tea prevents cancer have been investigated in cultured cells and animals, little is known in humans. Our goal in this project is to investigate the mechanisms by which tea might prevent oral cancers by using oral cells as tools. The purpose of this study is to find out what effects teahas on you and your oral cells.

Who can participate?
People between the ages of 18 to 60, including both current smokers and people who have never smoked.

What does the study involve?
You will be randomly allocated into one of four groups to drink 5 cups per day of either green tea, black tea, caffeinated water (same caffeine concentration as in tea), or a placebo drink (containing all elements of the tea beverages except the tea). You will drink two cups in the morning, two cups in the afternoon, and one cup after dinner. You will be instructed to drink by mouthfuls, holding each mouthful for 30 seconds to 1 minute. You will be assigned to each drink for four weeks each with a two-week break between each of the four drinks. You will undergo a general clinical evaluation every 2 weeks and a nutritional evaluation every week. You will provide a urine sample every week, a blood sample every 2 weeks, and a sample of oral cells (cytobrushing) every 2 weeks.

What are the possible benefits and risks of participating?
If you agree to take part in this study, there may or may not be direct medical benefit to you. However, we cannot promise that you will experience medical benefits from participating in this study. We hope the information learned from this study will benefit others in the future. There are little known risks associated with drinking tea or caffeinated water. Risks associated with drawing blood from your arm include pain, bruising, lightheadedness and, on rare occasion, infection or numbness. A trained professional will draw the blood sample so the chances of

these discomforts are minimal. Cytobrushing is a very low risk practice. It may cause minor bleeding, but this is unlikely.

Where is the study run from?
The study is run from the Lombardi Comprehensive Cancer Center of the Georgetown University in Washington DC, USA.

When is the study starting and how long is it expected to run for?
The study is starting in January 2006 and is expected to run for 4 years.

Who is funding the study?
The National Institutes of Health (USA).

Who is the main contact?
Dr Fung-Lung Chung

Contact information

Type(s)
Scientific

Contact name
Dr Fung-Lung Chung

Contact details
Lombardi Comprehensive Cancer Center
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Prevention of oral cancer by tea: a mechanism study

Study objectives

Our primary goal in this pilot project is to examine the molecular and cellular effects of tea treatment on oral cells in smokers. Cancer biomarkers studied include markers from the following pathways:
1. DNA damage
2. Metabolism of tobacco carcinogens
3. Growth arrest
4. p53 response

Ethics approval required
Old ethics approval format

Ethics approval(s)
MedStar Research Institute, Georgetown University Oncology Institutional Review Board, 14/12 /2005, ref: 2006-006

Study design
Single-center randomized double-blind placebo-controlled crossover trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
Oral cancer

Interventions
Intervention agents (each 5 cups per day):
1. Green tea
2. Black tea
3. Caffeinated water
4. Placebo water

The tea (400 mg of tea powder per cup), caffeinated water (same concentration as in tea drinks), and placebo (water) drinks will be provided by Mitsui Norin Co. Ltd., Tokyo, Japan.

Drinking protocol: Volunteers will receive a calibrated drinking container that they will fill with water. They will add 5 pouches of treatment for the day into the container and shake. Subjects will be instructed to follow a protocol including drinking two cups (200 ml each) in the morning, 2 cups (200 ml each) in the afternoon, and 1 cup (200 ml) after dinner. A standard method of

drinking will be described. Subjects will be instructed to drink by mouthfuls, holding each mouthful for 30 seconds to 1 minute to facilitate the uptake as recently demonstrated by Lee et al. Subjects will be told, during their initial visits, about the importance of practicing this method of drinking throughout the entire trial.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Markers of DNA damage (8-OH guanine)
2. Tobacco carcinogen metabolites (cyclic adducts)
3. Apoptosis

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/02/2006

Completion date
27/10/2010

Eligibility

Key inclusion criteria
1. Must be aged 18 to 60 years
2. Potential subjects should have been smoking for at least two years and be currently smoking at least 1/2 pack (10 cigarettes) per day
3. Subjects should be, in general, on a low flavonoid diet (low plant-based diet)

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40 current smokers (20 males and 20 females) and 24 non-smokers who never smoked (12 males and 12 females)

Key exclusion criteria

1. Allergic to tea or caffeine
2. Have oral leukoplakia or evidence of oral lesions
3. Regularly take medications containing caffeine, principally analgesics and 'cold' medicines (American Drug Index 1999)
4. Habitually drink more than two cups of coffee, tea, or caffeinated sodas per day
5. Habitually drink energy drinks (such as Red Bull, Jolt, Monster, etc.) each day
6. Drink more than two servings in one day of: 40% proof alcoholic beverages (3 oz), beer (12 oz), wine (6 oz), or any cocktail
7. Suffering from cancer
8. Have been treated with chemotherapy or radiotherapy within the past five years
9. Have cardiac arrhythmias or other heart disease or have been advised not to take excessive caffeine
10. Strict vegetarians
11. Taking alternative medications that have primarily an antioxidant effect (American Drug Index 1999)
12. Taking Vitamin A, C and E in doses > 1-1/2 x the RDA
13. Have serum levels of Vitamin A, serum carotenoids or alpha-tocopherol above the upper limits of normal
14. Have high blood pressure

Date of first enrolment
01/02/2006

Date of final enrolment
27/10/2010

Locations

Countries of recruitment
United States of America

Study participating centre
Lombardi Comprehensive Cancer Center
Washington, DC
United States of America
20057

Sponsor information

Organisation
Georgetown University (USA)

Sponsor details
Lombardi Comprehensive Cancer Center
3800 Reservoir Road
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+1 202 444 4000
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Sponsor type
University/education

Website
http://lombardi.georgetown.edu/index.html

ROR
https://ror.org/05vzafd60

Funder(s)

Funder type
Government

Funder Name
National Institutes of Health (USA) ref: CA113449

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

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	16/07/2012		Yes	No