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Dietary intakes in polyphenols and risk of cancers in the EPIC cohort

Submission date 10/10/2017	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 12/10/2017	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 17/08/2018	**Condition category** Cancer	[_] Individual participant data

Plain English summary of protocol

Background and study aims

Polyphenols are natural components of most plants. Major food sources are berries, fruits, coffee, tea, chocolate, wine, beer, vegetables, legumes and cereals. The most convincing evidence of the benefits of polyphenols for health is the protection against heart diseases. Besides this evidence, polyphenols may also play a role in the prevention of other diseases such as diabetes, neurodegenerative diseases and cancer. The protective properties of polyphenols against cancer have been well documented in a number of animal studies. Progress has been hampered by the limited availability of data on the content of polyphenols in foods. The main database on polyphenol content in foods used so far was developed by the United States Department of Agriculture. However, this database does not cover the wide diversity of polyphenols found in foods. To address this gap, a new comprehensive database on polyphenol contents in foods, Phenol-Explorer (www.phenol-explorer.eu), was recently created. This database represents major progress over the previous tools available. The aim of this study is to use the Phenol-Explorer database to explore the link between polyphenol intake and cancer risk.

Who can participate?

Healthy volunteers aged 30-70 participating in the European Prospective Investigation into Cancer and nutrition (EPIC) study

What does the study involve?

The EPIC participants' polyphenol intakes are estimated from questionnaires and 24-hour diet recalls. Cancer incidence is assessed using data from national or regional cancer registries, in order to find out if there are links between dietary polyphenol intake and the risk of cancer.

What are the possible benefits and risks of participating?

Due to the observational nature of the study there are no direct benefits for the patient, but they will contribute to the general advance in knowledge for the role of polyphenols in the prevention of cancer. No risks are involved other than minor incidents due to blood sampling.

Where is the study run from?

International Agency for Research on Cancer (France)

When is the study starting and how long is it expected to run for?
August 2010 to June 2014

Who is funding the study?
1. Institut National du Cancer, Paris (INCa)
2. Wereld Kanker Onderzoek Fonds (WCRF)
3. Hellenic Health Foundation

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
WCRF NL 2012/604

Study information

Scientific Title
Dietary intakes in polyphenols and risk of cancers in the EPIC cohort

Study objectives
Polyphenols are plant secondary metabolites ubiquitously found in plant-based foods. Given their antioxidant, antiproliferative and antiapoptotic properties and their average consumption of over one gram per day in most diets, the hypothesis is that some polyphenols protect against certain types of cancers.

Ethics approval required
Old ethics approval format

Ethics approval(s)
All the centers participating in the European Prospective Investigation into Cancer and Nutrition (EPIC) received ethics approval from their respective institutions before recruitment of the first participant.

International Agency for Research on Cancer Ethics Committee (IEC), 16/12/2014, ref: IEC Meeting 14-05

Study design
Prospective cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Community

Study type(s)
Other

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Cancer of the breast, prostate, endometrium, ovary, lung and thyroid

Interventions
Polyphenol intakes of the EPIC participants were estimated from dietary questionnaires (DQ) administered at baseline and from 24-hour diet recalls (24HDR) used in the calibration sub-study. A large polyphenol food composition table was first developed for the 24HDR foods and using the data available in Phenol-explorer, a unique and comprehensive database on polyphenol contents in foods that was created through a rigorous compilation of 60,000 original content values from the scientific literature (www.phenol-explorer.eu). Phenol-Explorer includes mean content values for 500 polyphenols in more than 450 food and beverage items. This consisted of matching ~20,000 food items between EPIC and Phenol-Explorer foods and correcting for loss during food processing using retention factors. The EPIC polyphenol food composition table was then linked to the DQ foods. Polyphenol intakes of the EPIC participants were calculated from both dietary assessment approaches across all EPIC centres. Dietary sources of polyphenols were then identified and variability within Europe was measured.

The trialists prospectively examined associations between dietary intakes in polyphenols in the different centres of the EPIC cohort and the risk of cancer during follow-up from baseline to 2007. Cox proportional hazards regression models were used to estimate relative risks and 95% confidence intervals. Multivariable models were adjusted on known risk factors for each cancer site studied to account for confounding. Interactions with potential effect modification factors,

which could provide new insights into mechanistic pathways, was investigated and stratified analyses performed when needed.

Intervention Type
Other

Primary outcome measure
Cancer incidence, assessed by record linkage with national or regional cancer registries approximately every two years during the study from baseline to 2007

Secondary outcome measures
Total and individual polyphenol intake across EPIC and socio-demographic factors associated with polyphenol intake, assessed at baseline, between 1992 and 2000 depending on the EPIC centre

Overall study start date
01/08/2010

Completion date
10/06/2014

Eligibility

Key inclusion criteria
1. Healthy volunteers residing within defined geographical areas, with some exceptions: women of a health insurance company for teachers and school workers (France), women attending breast cancer screening (Utrecht-The Netherlands, and Florence-Italy), mainly blood donors (most centers in Italy and Spain) and a cohort consisting predominantly of vegetarians (the 'health-conscious' group in Oxford, UK)
2. Aged 30-70

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
500,000 overall for 10 European countries, number varies by EPIC country/center

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/09/1992

Date of final enrolment

31/12/2000

Locations

Countries of recruitment
Denmark

England

France

Germany

Greece

Italy

Netherlands

Norway

Spain

Sweden

United Kingdom

Study participating centre
Paris, France
France
69076

Study participating centre
Athens, Greece
Greece
10679

Study participating centre
Aarhus, Denmark
Denmark
8000

Study participating centre

Copenhagen
Denmark
2100

Study participating centre
Tromso, Norway
Norway
9019

Study participating centre
Malmo, Sweden
Sweden
21119

Study participating centre
Umea, Sweden
Sweden
90187

Study participating centre
Utrecht, Netherlands
Netherlands
3584

Study participating centre
Bilthoven, Netherlands
Netherlands
3721

Study participating centre
Oxford, UK
United Kingdom
OX1 2JD

Study participating centre

Norfolk, UK
United Kingdom
NR31 0ED

Study participating centre
Heidelberg, Germany
Germany
69120

Study participating centre
Potsdam, Germany
Germany
14558

Study participating centre
Asturias, Spain
Spain
33005

Study participating centre
Guipuzcoa, Spain
Spain
20013

Study participating centre
Navarra, Spain
Spain
31003

Study participating centre
Murcia, Spain
Spain
30003

Study participating centre

Granada, Spain
Spain
18011

Study participating centre
Turin, Italy
Italy
10126

Study participating centre
Milan, Italy
Italy
20133

Study participating centre
Florence, Italy
Italy
50139

Study participating centre
Naples, Italy
Italy
80138

Study participating centre
Ragusa, Italy
Italy
97100

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IARC, Lyon, France
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Study participating centre

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Sponsor information

Organisation
International Agency for Research on Cancer

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Sponsor type
Research organisation

ROR
https://ror.org/00v452281

Funder(s)

Funder type
Research organisation

Funder Name
Institut National du Cancer, Paris (INCa)

Funder Name
Wereld Kanker Onderzoek Fonds (WCRF)

Funder Name
Hellenic Health Foundation

Results and Publications

Publication and dissemination plan

Publication in peer reviewed journal.

Intention to publish date
31/12/2017

Individual participant data (IPD) sharing plan
The complete procedure used to estimate polyphenol intakes will be published in the form of a methodological manuscript and with that the EPIC polyphenol database will be made available as an online supplement. Additionally, the following link can be consulted for further details regarding access to the EPIC data: https://epic.iarc.fr/docs/EPIC_Access_Policy_and_Guidelines.pdf

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results:	01/09/2018		Yes	No