

Inflammatory potential of the diet and risk of gastric cancer in the European Prospective Investigation into Cancer and Nutrition (EPIC) study

Submission date 01/08/2017	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 11/09/2017	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 12/04/2018	Condition category Cancer	☐ Individual participant data

Plain English summary of protocol

Background and study aims

Chronic (long-term) inflammation plays a critical role in the development of the two major types of gastric (stomach) cancer. Several foods, nutrients, and non-nutrient food components seem to be involved in chronic inflammation. The aim of this study is to assess the link between the inflammatory potential of the diet and the risk of gastric cancer, overall and for the two major types of gastric cancer: cardia cancers and non-cardia cancers.

Who can participate?

People aged 30-70 who participated in the European Investigation into Cancer and Nutrition (EPIC) study

What does the study involve?

Dietary information is collected using questionnaires and the inflammatory potential of the diet is assessed. Gastric cancer incidence is assessed using population cancer registries and national or regional mortality registries in most of the participating countries. In France, Germany and Greece a combination of approaches are used, including cancer and pathology registries, health insurance records, and active follow-up contacting the participants or their next-of-kin.

What are the possible benefits and risks of participating?

There are no direct benefits for the patient, but they will contribute to the general advance in knowledge for the prevention of diseases. No risks are involved other than minor incidents due to blood sampling.

Where is the study run from?

1. International Agency for Research on Cancer (France)
2. Imperial College London (UK)

When is the study starting and how long is it expected to run for?
October 2015 to December 2016

Who is funding the study?

1. Health Research Fund (FIS)
2. European Commission (DG-SANCO)
3. Bundesministerium für Bildung und Forschung
4. Hellenic Health Foundation (Greece)
5. Associazione Italiana per la Ricerca sul Cancro
6. Consiglio Nazionale delle Ricerche
7. Ministerie van Volksgezondheid, Welzijn en Sport
8. Netherlands Cancer Registry (NKR)
9. World Cancer Research Fund
10. Red Temática de Investigación Cooperativa en Cáncer of the Instituto de Salud Carlos III
11. FEDER funds/European Regional Development Fund (ERDF)
12. Swedish Research Council and County Councils of Skåne and Västerbotten (Sweden)
13. Cancer Research UK

Who is the main contact?

Dr Antonio Agudo

Contact information

Type(s)

Scientific

Contact name

Dr Antonio Agudo

Contact details

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Additional identifiers

Protocol serial number

PI15_0639_1

Study information

Scientific Title

Inflammatory potential of the diet and risk of gastric cancer in the European Prospective Investigation into Cancer and Nutrition (EPIC) study

Study objectives

Inflammation is related to carcinogenesis, and specially to tumors from the GI tract. Diet modulates inflammation and many dietary components have been related with levels of

circulating inflammatory markers. Therefore, the inflammatory potential of diet can be associated with the risk of gastric cancer.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Clinical Research Ethics Committee (Comité de Investigación Clínica) of the Bellvitge University Hospital, L'Hospitalet de Llobregat (Barcelona), Spain, 23/03/2015, ref. PR102/15

All other centres received ethics approval before recruitment of the first participant

Primary study design

Observational

Study design

Prospective cohort study

Study type(s)

Other

Health condition(s) or problem(s) studied

Gastric cancer (malignant carcinoma)

Interventions

Dietary information collected by means of dietary history questionnaire or food-frequency questionnaires. The dietary inflammatory potential was assessed by means of an inflammatory score of the diet (ISD), calculated using 28 dietary components and their corresponding inflammatory scores. Outcomes assessed by record linkage with population cancer registries and national or regional mortality registries in most of the participating countries. In France, Germany and Greece an active follow-up used a combination of approaches, including cancer and pathology registries, health insurance records, and active follow-up contacting the participants or their next-of-kin. Updates of the endpoints (as well as vital status) were done approximately every two years. The association between the ISD and gastric cancer risk was estimated by hazard ratios (HR) and 95%-confidence intervals (CI) calculated by multivariate Cox regression models adjusted for confounders.

Intervention Type

Other

Primary outcome(s)

Gastric cancer incidence, assessed by record linkage with population cancer registries and national or regional mortality registries approximately every two years during the study

Key secondary outcome(s)

Gastric cancers according to anatomical site: cardia or non-cardia, assessed by record linkage with population cancer registries and national or regional mortality registries approximately every two years during the study

Completion date

31/12/2016

Eligibility

Key inclusion criteria

1. Healthy volunteers resident in each study centre. Different settings by centre: general population, blood donors, participants in screening programs
2. Aged 30-70

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

Denmark

France

Germany

Greece

Italy

Netherlands

Norway

Spain

Sweden

Study participating centre

Paris

France

94076

Study participating centre

Athens

Greece

10679

Study participating centre

Aarhus

Denmark

8000

Study participating centre

Copenhagen

Denmark

2100

Study participating centre

Tromso

Norway

9019

Study participating centre

Malmo

Sweden

21119

Study participating centre

Umea

Sweden

90187

Study participating centre
Utrecht
Netherlands
3584

Study participating centre
Bilthoven
Netherlands
3721

Study participating centre
Oxford
United Kingdom
OX1 2JD

Study participating centre
Norfolk
United Kingdom
NR31 0ED

Study participating centre
Heidelberg
Germany
69120

Study participating centre
Potsdam
Germany
14558

Study participating centre
Asturias
Spain
33005

Study participating centre
Guipúzcoa
Spain
20013

Study participating centre
Navarra
Spain
31003

Study participating centre
Murcia
Spain
30003

Study participating centre
Granada
Spain
18011

Study participating centre
Turin
Italy
10126

Study participating centre
Milan
Italy
20133

Study participating centre
Florence
Italy
50139

Study participating centre

Naples

Italy
80138

Study participating centre**Ragusa**

Italy
97100

Study participating centre**IARC**

Lyon
France
69372

Study participating centre**Imperial College London**

United Kingdom
SW7 2AZ

Sponsor information**Organisation**

Catalan Institute of Oncology

ROR

<https://ror.org/01j1eb875>

Funder(s)**Funder type**

Government

Funder Name

Health Research Fund (FIS)

Funder Name

European Commission (DG-SANCO)

Funder Name

Bundesministerium für Bildung und Forschung

Alternative Name(s)

Federal Ministry of Research, Technology and Space, Bundesministerium für Bildung und Forschung, Federal Ministry of Education and Research, BMBF

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Germany

Funder Name

Hellenic Health Foundation (Greece)

Funder Name

Associazione Italiana per la Ricerca sul Cancro

Alternative Name(s)

Italian Association for Cancer Research, The Italian Association for Cancer Research, AIRC

Funding Body Type

Private sector organisation

Funding Body Subtype

Associations and societies (private and public)

Location

Italy

Funder Name

Consiglio Nazionale delle Ricerche

Alternative Name(s)

National Research Council, Consiglio Nazionale delle Ricerche (IT), The National Research Council (Cnr), National Research Council of Italy, National Research Council (Italy), Italy, Consiglio Nazionale delle Ricerche, CNR

Funding Body Type

Government organisation

Funding Body Subtype

Research institutes and centers

Location

Italy

Funder Name

Ministerie van Volksgezondheid, Welzijn en Sport

Alternative Name(s)

Dutch Ministry of Health, Welfare and Sport, VWS

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Netherlands

Funder Name

Netherlands Cancer Registry (NKR)

Funder Name

World Cancer Research Fund

Alternative Name(s)

World Cancer Research Fund UK, World Cancer Research Fund International, WCRF International, WCRF, WCRF UK

Funding Body Type

Government organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Funder Name

Red Temática de Investigación Cooperativa en Cáncer of the Instituto de Salud Carlos III

Funder Name

FEDER funds/European Regional Development Fund (ERDF)

Funder Name

Swedish Research Council and County Councils of Skåne and Västerbotten (Sweden)

Funder Name

Cancer Research UK

Alternative Name(s)

CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2018		Yes	No