

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

<b>Submission date</b> 01/08/2017	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 11/09/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 12/04/2018	<b>Condition category</b> Cancer	<input type="checkbox"/> 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**

Av. Gran Via de l'Hospitalet, 199-203  
2nd floor  
Barcelona  
Spain  
08908

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

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

## 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

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 measure**

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

**Secondary outcome measures**

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

**Overall study start date**

01/10/2015

**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

**Age group**

Adult

**Sex**

Both

**Target number of participants**

500000 overall for 10 European countries. variable number by 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

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

**Sponsor details**

Av. Gran Via de l'Hospitalet, 199-203

2nd floor

Barcelona

Spain

08908

**Sponsor type**

Hospital/treatment centre

**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 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), National Research Council of Italy, National Research Council (Italy), Italy, Consiglio Nazionale delle Ricerche, CNR

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**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, WCRF, WCRF UK

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Other non-profit organizations

**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, CRUK

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Other non-profit organizations

**Location**

United Kingdom

## Results and Publications

**Publication and dissemination plan**

Publication in peer reviewed journal.

**Intention to publish date**

01/08/2017

**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?
<a href="#">Results article</a>	results	01/04/2018		Yes	No