

# 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

### 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

### **Study design**

Prospective cohort study

### **Primary study design**

Observational

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

