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Fruit juice, fruit, and cardiovascular diseases

Submission date
16/01/2018

Recruitment status
No longer recruiting

Registration date
29/01/2018

Overall study status
Completed

Last Edited
15/01/2019

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Dietary guidelines for replacing fruit with pure fruit juice differ between countries from 'half of the recommended fruit intake may be replaced by pure fruit juice' up to 'keep consumption of pure fruit juice to a minimum'. Fruit juice contains less dietary fiber and vitamin C than whole fruits. However, pure fruit juice still contains a high concentration of polyphenols which might reduce the risk of cardiovascular (heart) disease (CVD). Research on pure fruit juice is limited to risk factors of CVD such as blood pressure and serum cholesterol. The aim of this study is to investigate the association of pure fruit juice and fruit consumption with CVD, and to assess the association between fruit juice consumption and CVD for low and high fruit consumers.

Who can participate?
Participants from the EPIC-NL study: men and women aged 20 – 65 years selected from random samples of the Dutch population in three towns in the Netherlands (Amsterdam, Doetinchem, Maastricht), and women from the Dutch town Utrecht or its vicinity, who participated in a breast cancer screening program

What does the study involve?
A food frequency questionnaire is used to estimate fruit and fruit juice consumption of 35,620 Dutch men and women from the EPIC-NL study. CVD, coronary heart disease (CHD) and stroke morbidity (illness) and mortality (death) data are obtained through linkage with national registries.

What are the possible benefits and risks of participating?
This study is an observational study and therefore there are neither benefits nor risks of participating. However, participating will contribute to more knowledge about the association between fruit juice consumption and CVD.

Where is the study run from?
National Institute for Public Health and the Environment (RIVM) and the Julius Center for Health Sciences and Primary Care (Netherlands)

When is the study starting and how long is it expected to run for?
April 2015 to December 2017

Who is funding the study?
1. “Europe against Cancer” Programme of the European Commission (DG SANCO)
2. The Dutch Ministry of Health, Welfare and Sports (VWS)
3. The Netherlands Organisation for Health Research and Development (ZonMW)
4. The World Cancer Research Fund (WCRF)

Who is the main contact?
1. F.R. Scheffers
2. W.M.M. Verschuren
3. A. Blokstra

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MEC-TNO 93/01

Study information

Scientific Title
Pure fruit juice and fruit consumption and the risk of cardiovascular diseases: the EPIC-NL study

Study objectives
Pure fruit juice contains less dietary fiber and vitamin C than whole fruits. However, pure fruit juice still contains a high concentration of polyphenols which might reduce the risk of CVD. Therefore, pure fruit juice may protect against CVD.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Prospect cohort: Institutional board of the University Medical Center Utrecht, 28/7/1993, ref: WOM-93/090
2. MORGEN cohort: Medical Ethical Committee of TNO Nutrition and Food Research, 06/04 /1993, ref: MEC-TNO 93/01

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

Health condition(s) or problem(s) studied
Cardiovascular diseases, coronary heart diseases and stroke

Interventions
A validated FFQ was used to estimate the dietary intake of 35,620 Dutch men and women from the EPIC-NL study. CVD, CHD and stroke morbidity and mortality data were obtained through linkage with national registries. Cox regression was used to estimate hazard ratios (HRs) and 95% confidence intervals (CIs) adjusted for several counfounders. Interactions with potential effect modification factors were investigated.

Intervention Type
Other

Primary outcome measure
CVD morbidity and mortality data obtained through linkage with national registries from baseline (1993 – 1993) to 2010

Secondary outcome measures
CHD and stroke morbidity and mortality data obtained through linkage with national registries from baseline (1993 – 1993) to 2010

Overall study start date
01/04/2015

Completion date
01/12/2017

Eligibility

Key inclusion criteria
The EPIC-NL study consists of two cohorts:
1. The MORGEN cohort consists of men and women aged 20 – 65 years selected from random samples of the Dutch population in three towns in the Netherlands (Amsterdam, Doetinchem, Maastricht)
2. The Prospect cohort consists of women from the Dutch town Utrecht or its vicinity, who participated in a breast cancer screening program

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
40,000 overall for EPIC-NL

Key exclusion criteria
1. Missing food-frequency questionnaire (FFQ)
2. Extremely low or high reported energy intake (i.e. those in the lowest or highest 0.5% of the ratio of energy intake over basal metabolic rate)

3. No permission to link with the Dutch Hospital Discharge Diagnosis Database
4. Missing vital status
5. Missing cause of death
6. Prevalent CVD at baseline based on self-report or identified through linkage with the Dutch Hospital Discharge Diagnosis Database
7. Prevalent Diabetes Mellitus at baseline based on self-report, or missing data on confounders

Date of first enrolment
11/01/1993

Date of final enrolment
24/12/1993

Locations

Countries of recruitment
Netherlands

Study participating centre
National Institute for Public Health and the Environment (RIVM)
Antonie van Leeuwenhoeklaan 9
Bilthoven
Netherlands
3721 MA

Study participating centre
Julius Center for Health Sciences and Primary Care
Huispost nr. STR 6.131
PO Box 85500
Utrecht
Netherlands
3508 GA

Sponsor information

Organisation
Netherlands Organisation for Scientific Research (NWO)

Sponsor details
PO Box 93138
The Hague
Netherlands
2509 AC

Sponsor type
Research organisation

ROR
https://ror.org/01bnjb948

Funder(s)

Funder type
Government

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
ZonMw

Alternative Name(s)
Netherlands Organisation for Health Research and Development

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Netherlands

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
European Commission (DG SANCO)

Results and Publications

Publication and dissemination plan
Submission to peer-reviewed journal directly after the registration is finished.

Intention to publish date
01/07/2018

Individual participant data (IPD) sharing plan
The datasets analysed during the current study and all EPIC-NL data are available upon request for scientific research (no commercial aims) and after signing a material transfer agreement. An EPIC-NL data-request form needs to be filled out and sent to J.J.Metselaar@umcutrecht.nl or epicnl@umcutrecht.nl. Data will be-anonymised to the extent that they are not tracable to any individual, e.g. no names, adresses, birth dates etc. will be provided (only age in years). A data management fee is requested.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2019	15/01/2019	Yes	No