Trial Description

Title

The German Study on Tobacco Use

Trial Acronym

DEBRA

URL of the trial

http://www.debra-study.info

Brief Summary in Lay Language

The DEBRA study ran in the first funding period from June 2016 to April 2019 (DRKS00011322) with a focus on the consumption of tobacco products/smoking behaviour in the German population. The second funding period (Federal Ministry of Health, BMG) will start in June 2019.
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Summary:
Electronic inhalation products (e-inhalation products) such as electronic cigarettes (e-cigarettes) and heat-not-burn products are being increasingly used by adolescents and adults in Germany as an alternative or complement to conventional tobacco smoking. However, up-to-date, detailed and representative data are missing on the prevalence (frequency) and trends of usage, consumption patterns, associated factors (particularly on the association with tobacco smoking cessation and initiation), and views and harm perception of these products.
From a health policy perspective, such data are important since these products can pose both, risks (health risks, "gateway" to smoking) and opportunities (harm reduction, smoking cessation aid) for public health. The DEBRA study consists of face-to-face household interviews of representative samples of the German population aged 14 and over (approx. 2,000 persons per survey wave = every second month, with a total of 17 waves over a period of 3 years). The study aims to (1) monitor the prevalence of the use of e-inhalation products at regular intervals; (2) record relevant consumption patterns in detail and monitor them over time; (3) analyse the relationship between the consumption of e-inhalation products and the initiation/quitting of tobacco smoking, as well as associations with socio-demographic consumer characteristics; and (4) assess views and harm perception of these products.

Respondents who are current tobacco smokers (daily or occasional) or recent ex-smokers (<=12 months since smoking cessation) at baseline will be re-contacted by phone after six month (follow-up) and asked about the rates, duration and success of quit attempts (if so), triggers of quit attempts, exposure to health professionals' advice on quitting, and use of behavioural (medical counselling, group therapy) and pharmacological (nictoine replacement, drugs) cessation aids, including e-cigarettes.

The methodology of DEBRA is closely aligned to the Smoking Toolkit Study, which will allow international comparisons of data.

Brief Summary in Scientific Language

The DEBRA study ran in the first funding period from June 2016 to April 2019 (DRKS00011322) with a focus on the consumption of tobacco products/smoking behaviour in the German population. The second funding period (Federal Ministry of Health, BMG) will start in June 2019.
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In the course of an amendment from the 18.03.2019, the extension of the study for a further 3 years was anounced to the Ethik-Kommission Medizinischen Fakultät Heinrich-Heine-Universität Düsseldorf, and has been approved by the Committee on 17.04.2019.

Do you plan to share individual participant data with other researchers?

[---]*

Description IPD sharing plan

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Organizational Data

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DRKS-ID: **DRKS00017157**

- Date of Registration in DRKS: **2019/05/22**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **5386R , Ethik-Kommission an der Medizinischen Fakultät der Heinrich-Heine-Universität Düsseldorf**

Secondary IDs

- Other Secondary-ID: **DRKS00011322 (DRKS-ID Studienteil 1/study part 1)**

Health condition or Problem studied

- ICD10: **F17.2 - Mental and behavioural disorders due to use of tobacco; Dependence syndrome**
- Free text: **Smoking behaviour**

Interventions/Observational Groups

- Arm 1: <style fontName='DejaVu Sans' isBold='true'>All participants of the computer-assisted, face-to-face household survey:
  Over a period of at least 3 years, every two months, a new sample of approximately 2,000 respondents aged 14 years and older will complete the survey (17 waves = approximately 37,000 respondents).

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  Smokers and recent ex-smokers (<=12 months) of these samples:
  At baseline and six months later, this group will answer detailed questions about rates, duration and success of quit attempts, internal and external triggers of quit attempts, exposure to health professionals' advice on quitting, and use of behavioural and pharmacological cessation aids, including electronic cigarettes.

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  Current or recent users of electronic inhalation products of these samples: Will be asked in detail about their consumption behaviour, harm perception of these products, motivation for and experience with these electronic inhalation products.</style>

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Epidemiological study**
- Allocation: **Other**
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Blinding: **[---]***

- Who is blinded: **[---]***
- Control: **Other**
- Purpose: **Other**
- Assignment: **Other**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Primary aim of the DEBRA study is to track key variables relating to patterns and trends of consumption of electronic inhalation products (e.g., e-cigarettes, heat-not-burn products), tobacco smoking and quitting in Germany, and to provide such nationally representative data to inform tobacco control policies, cessation strategies, and future scientific studies. Data will be collected via computer-assisted household interviews at baseline. Current tobacco smokers and recent ex-smokers will be followed-up 6 months later.

Secondary Outcome

Secondary aim is to compare our primary endpoints with comparable data from other international surveys, particularly from England.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- other **Deutschlandweit (Germany nationwide)**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2019/06/15**
- Target Sample Size: **34000**
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Monocenter/Multicenter trial: **Monocenter trial**

- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **14 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

Informed consent

Exclusion criteria

barriers in language, moderate-severe cognitive impairment

Addresses

- **Primary Sponsor**

Medical Faculty of the Heinrich-Heine-University Duesseldorf
Moorenstr. 5
40225 Düsseldorf
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **www.uniklinik-duesseldorf.de**

- **Contact for Scientific Queries**

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Sources of Monetary or Material Support

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

Federal Ministry of Health (BMG) Germany
53123 Bonn
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*