Trial Description

Title

ELITE study - Nutrition, lifestyle and individual information for the prevention of stroke, dementia and heart attack

Trial Acronym

ELITE

URL of the trial

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Brief Summary in Lay Language

In the ELITE study comprehensive data on cardiovascular risk factors, dietary habits, physical activity, cognitive function, depression and taking medication are to be detected prospectively. Individual reasons for failure of prevention recommendations should be recognized.
By implementing information on an individual's risk profile based on previously published recommendations prevention or deterioration of risk factors (eg hypertension) and end-organ damage should be prevented. The study examines and should identify the main individual factors that contribute significantly to the progression of end-organ damage. This is particularly important for the development of cognitive deficits because reliable data on this are rare.

Brief Summary in Scientific Language

It is a prospective registry study with a 5-year observation period.

Organizational Data

- DRKS-ID: **DRKS00006813**
- Date of Registration in DRKS: **2014/10/07**
- 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.: **34/6/14 , Ethik-Kommission der Medizinischen Fakultät der Georg-August-Universität Göttingen**

Secondary IDs

Health condition or Problem studied

- ICD10: **I10-I15 - Hypertensive diseases**
- ICD10: **I60-I69 - Cerebrovascular diseases**
- ICD10: **I20-I25 - Ischaemic heart diseases**
- ICD10: **E65-E68 - Obesity and other hyperalimentation**
- ICD10: **I48 - Atrial fibrillation and flutter**
- ICD10: **F01 - Vascular dementia**
- ICD10: **F06.7 - Mild cognitive disorder**
- ICD10: **F32 - Depressive episode**

Interventions/Observational Groups

- Arm 1: **After the baseline survey data collection is carried out on an annual basis. There are questionnaires used to be filled out by the participants, more data are collected in interviews, laboratory values are taken from medical records if they are available. Patients will receive an overview of their individual risk factors using previously published prevention recommendations.**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Prevention**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

1 What is the prevalence of major vascular risk factors (hypertension, Diab. mell., smoking, obesity, lipid disorders, stress at work)?
2 Sucess of blood pressure controll (office-RR <140/90 mmHg or self-measurement <135/85 mmHg)?
3 How is the awareness of the individual participant´s risk factors?
4 What is the prevalence of dementia or cognitive impairment in individuals with

cardiovascular risk factors or comorbidities?
5 What is the extent of physical activity?
6 How is the nutrition in particular regarding meats, fruits / vegetables, salt, alcohol, coffee?
7 What is the treatment adherence (recommendations after hospitalization or Guidelines) to diseases such as stroke or heart attack?
8 How common is atrial fibrillation in different age groups and the proportion of patients with oral anticoagulation (Vit.-K-antagonists or NOAC)?
9 Which recommendations for the prevention of cardiovascular disease or dementia patients consider as feasible?
10 Which obstacles exist in the implementation of recommended lifestyle modifications?
11 How often are hospital admissions in the region in different age groups?
12 How often are depressive disorders and what is the degree of treatment?
13 What are the connections between depressive disorders and other cardiovascular risk factors?
14 What are the connections between eating behavior or diets and depression?
15 How correlate physical activity and prevalence and incidence of depressive disorders?

Secondary Outcome

1. Change of the risk factors (parameters of the baseline survey) during the observation after 5 years.
2. Which are the differences between individuals with change of risk factors compared to those without?
3 How does individual behavior change with knowledge of the risk factors?
4 How is the treatment adherence?
5. Identification of lifestyle-recommendations that are regarded as acceptable or successfully by participants.
6. Do prevention-strategies impact vascular events?
7. Vascular event rates as a function of the risk factors.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **St.-Josefs-Hospital, Cloppenburg**

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2014/10/15**
- Target Sample Size: **5000**
- Monocenter/Multicenter trial: **Monocenter trial**

Planned/Actual: **Planned**

(Anticipated or Actual) Date of First Enrollment: **2014/10/15**

Target Sample Size: **5000**

Monocenter/Multicenter trial: **Monocenter trial**

- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

Informed consent
Age >= 18 years

Exclusion criteria

Age < 18 years
Obvious difficulty to track the participants

Addresses

- **Primary Sponsor**

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Sources of Monetary or Material Support

- **Private sponsorship (foundations, study societies, etc.)**

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Status

- Recruitment Status: **Recruiting planned**
- 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.*