Trial Description

Title

CDRM Study: Computer-assisted diabetes risk management - evaluation of a medical care approach to support secondary and tertiary prevention of diabetes mellitus and its complications

Trial Acronym

CDRM Studie

URL of the trial

[---]*

Brief Summary in Lay Language

The study will analyse a new care approach for diabetes patients. The abbreviation CDRM stands for -computer-assisted diabetes risk management-. Research will focus on the evaluation of this approach using an electronic, personal health record (PHR) as data and information platform in combination with a CDRM tool to better manage the complex disease. It promises to improve diabetes prevention and therapy and aims to identify and reduce the risks of long-term complications and secondary illness.

Brief Summary in Scientific Language

The CDRM study will evaluate a newly developed approach to improve management and secondary prevention in diabetes care. The research will explore the impact of an medical care intervention via a computer-assisted diabetes risk management system (CDRMS) on compliance and outcome The focus will be on the effect on patients' diabetes and diabetes complication risk profiles, medical effectiveness and patients- reported outcomes.

Organizational Data

- DRKS-ID: **DRKS00000056**
- Date of Registration in DRKS: **2008/12/08**
- 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.: **92/07 , Ethik-Kommission des Fachbereichs Medizin der Philipps-Universität Marburg**

Secondary IDs

Health condition or Problem studied

- Free text: **Type 2 Diabetes**
- ICD10: **E11 - Non-insulin-dependent diabetes mellitus**

Interventions/Observational Groups

- Arm 1: **Using the study design, we will determine the effects of a computer-assisted, multifaceted diabetes risk management system. It consists of a combination of several telematic instruments used by the patient, the general practitioner and medical specialists. Key functionalities of the network supporting the care approach are the software integration of GP practices and an automated data recording via digital devices of blood glucose meters. Furthermore, the CDRM-Tool, Accu-Chek Mellibase a client server application of Roche Diagnostics GmbH is connected to the overall system. It generates reports - one for the physician and one for the patient - on the current health status, describing the 10 year risk to develop a major complication (separately for myocardial infarction, stroke, kidney failure, blindness, amputation) and the potential to reduce this risk. These reports shall be used during consultations to help doctors and patients to communicate about diabetes associated risks and individual potential. The GP report shall ease doctor s decision on therapy and medication. The patient report shall inform the patient to improve compliance and to strengthen empowerment. The CDRMS gains this information by correlating the basic patient data plus the data from recent medical findings with the most recent diabetes research evidence.**
  GPs of this intervention group will only get advice concerning how to use the CDRMS properly. The study design does not allow the use of further (extra) intervention measures others than specified in this protocol. There will be no further recommendations from the research team to GPs how to decide on individual therapy or medication.
- Arm 2: **GPs of the control group won't get any instructions or recommendations how to treat patients. The control group shall represent the diabetes care standard in the study region.**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **Open (masking not used)**
- Who is blinded: **[---]***
- Control: **Active control**
- Purpose: **Prevention**
- Assignment: **Parallel**

Study Type: **Interventional**

Study Type Non-Interventional: **[---]***

Allocation: **Randomized controlled trial**

Blinding: **Open (masking not used)**

Who is blinded: **[---]***

Control: **Active control**

Purpose: **Prevention**

Assignment: **Parallel**

- Phase: **[---]***
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

HbA1c and other metabolic parameters at last observation, incidence of typical diabetes complications and changes of complication risk profile during observation time

Secondary Outcome

patients reported outcomes (EuroQol, DTSQ) || Impact of the intervention on process and utilisation of care || impact of the intervention on patient knowledge and behaviour || Impact of the intervention on clinical effectiveness

Countries of recruitment

- DE **Germany**

Locations of Recruitment

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2009/03/06**
- Target Sample Size: **400**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **40 Years**
- Maximum Age: **68 Years**

Additional Inclusion Criteria

Diagnosed with Type 2 Diabetes Mellitus
Older than 40 years at the time of diabetes diagnosis
Participating in the Diabetes RSAV-DMP (German state health insurance DMP)

Exclusion criteria

Pregnant
Dementia, psychoses, or other illness that would hinder compliance
Serious illness such as: cancer, immune deficiency syndrome (HIV), genetic lipid disorder (e.g. autosomal dominant familial hypercholesteremia)
Malabsorption syndromes such as colitis and Morbus Crohns disease.
Bed-ridden or required supportive care
Cardiac insufficiency > NYHA class II
Chronic metabolic storage illnesses such as Morbus Wilson or Amyloidosis.
Endocrinologic diseases with elevated anti-insulin hormone (e.g. hyperthyreosis, pheochromocytoma, acromegaly.
Chronic inflammatory diseases.
Chronic therapy with corticosteroids, diazoxide.
Pancreatic Diabetes mellitus (e.g. alcoholism, chronic pancreatitis, pancreatic resection)
Any illness that would prevent the active involvement of the patient in the present study

Addresses

- **Primary Sponsor**

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Contact for Scientific Queries

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Sources of Monetary or Material Support

- **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

InterComponentWare AG

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **http://www.icw-global.com/de/de/**

- **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

Gesellschaft für Telematik im Gesundheitswesen mbH Co KG

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

- **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

Roche Diagnostics GmbH

Commercial (pharmaceutical industry, medical engineering industry, etc.)

Roche Diagnostics GmbH

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

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2011/05/04**

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.*