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PrImary Care management for optimized ANtithrombotic Treatment

Submission date 27/02/2012	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 13/04/2012	**Overall study status** Completed	
Last Edited 24/06/2020	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
Antithrombotic drugs reduce the formation of blood clots. Many patients receive antithrombotic treatment because of an irregular heartbeat or recurrent blood clots. Traditional antithrombotic treatments (e.g. with coumarins or aspirin) may lead to severe or even lethal adverse events such as bleeding. The aim of this study is to investigate whether a best practice model that includes patient education and regular monitoring by a healthcare assistant can help to improve antithrombotic management in general practices by reducing the number of severe events.

Who can participate?
Adult patients who are expected to take antithrombotic tablets for the rest of their lives and who regularly visit their general practitioner.

What does the study involve?
Participating family practices are randomly assigned to either the intervention group or the standard care group. Patients in the intervention group receive a more intensive treatment program involving general practitioners, health care assistants and education. The healthcare assistants in particular regularly monitor patients by means of a structured checklist whenever they visit the practice. This is so the practice team can figure out certain problems with medication interaction immediately and can help to solve the problems at once. The standard care group continue to receive standard healthcare based on the provided guidelines.

What are the possible benefits and risks of participating?
Intensified antithrombotic care in the intervention group may lead to improved outcomes. As the study is not concerned with drug effectiveness and the patients continue their assigned treatment, additional risks are not expected.

Where is the study run from?
The study will be run by the Institute of General Practice and involve 46 practices in Germany

When is the study starting and how long is it expected to run for?
May 2012 to April 2015

Who is funding the study?
German Federal Ministry of Education and Research

Who is the main contact?
Prof. Siebenhofer-Kroitzsch
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Study website
http://www.allgemeinmedizin.uni-frankfurt.de/forschung1/picant.html

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
(BMBF) 01GY1145

Study information

Scientific Title
PrImary Care management for optimized ANtithrombotic Treatment: a cluster-randomized controlled trial

Acronym
PICANT

Study objectives
We expect that a best practice model that applies major elements of case management, including patient education, can improve antithrombotic management in primary health care in

terms of reducing major thromboembolic and bleeding events in the intervention versus the standard care group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Department of Medicine, J.W. Goethe University Hospital, Frankfurt [Fachbereich Medizin, Klinikum der J.W. Goethe Universität Frankfurt], 14/11/2011, ref: E 191/11

Study design
Single-center cluster randomized controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
GP practice

Study type(s)
Treatment

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
Patients with long-term indication for antithrombotic treatment

Interventions
The trial interventions will be a multifaceted intervention involving general practitioners (GPs), health care assistants (HCA) and patients. To assess adherence to medication and symptoms in patients, as well as detect complications early, HCAs will be trained in case management and will regularly monitor patients by means of the Coagulation-Monitoring-List (Co-MoL). Practice routines will be improved. For patients the intervention will include patient information, treatment monitoring via the Co-MoL and motivation to perform self-management.

The control will consist of standard primary health care based on the provided guidelines without any case-management intervention and specific patient education.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure

Combined endpoint of all thromboembolic events requiring hospitalization and all major bleeding complications

Secondary outcome measures
1. Mortality
2. Frequency and duration of hospitalization
3. Number of recurrent strokes, major bleeding and thromboembolic complications
4. Treatment-related quality of life analysis (EQ 5 D;The EuroQol Group. Health Policy 1990 Dec; 16(3):199-208)
5. Number of treatment interactions
6. Number of adverse events
7. Quality of anticoagulation control (Siebenhofer A, Rakovac I, Kleespies C, Piso B, Didjurgeit U.
8. Self-management of oral anticoagulation reduces major outcomes in the elderly. A randomized controlled trial. Thromb Haemost 2008; 100(6):1089-1098)
9. Cost effectiveness evaluations (Drummond et al Methods for the Economic Evaluation of Health care Programmes. 3rd edition, Oxford University Press 2005)
10. Qualitative study analysis to describe the experience of study participants (patients, HCA, GPs) on the basis of semi-structured interviews

Overall study start date
01/05/2012

Completion date
30/04/2015

Eligibility

Key inclusion criteria
Trial sites (General practices):
1. Working as a general practitioner inclusive specialists in internal medicine
2. Doctors agreement that health care assistants (HCAs) from the practice are allowed to participate in a structured educational course and perform specific case management duties afterwards
3. Practice provides health services to persons with German statutory health insurance
4. Practice software with the facility to detect eligible patients requiring antithrombotic treatment
5. Investigating physician agrees to the contractual obligations of the trial

Patient
1. All patients (age ≥18 years)
2. Long term indication for oral anticoagulation: atrial fibrillation, recurrent venous thromboembolism, pulmonary embolism, mechanical heart prosthesis and others such as; hereditary coagulopathy, intracardial thrombosis
3. Given indication for coumarins, antiplatelet therapies or the new antithrombotic agents rivaroxaban and dabigatran
4. Patient is capable to give a free and written informed consent to participate in the trial, to fill in questionnaires and to participate in telephone interviews.
5. Care is provided by a general practitioner (GP) working at a trial site (at least one contact in the last 12 months)
6. Patient is legally competent to sign any documents

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
345 per group, 690 in total

Total final enrolment
736

Key exclusion criteria
Patients:
1. Lack of German language skills
2. Diseases causing life expectancy of < 6 months
3. Dementia (GPs assessment) [less than score 26 in Mini Mental State Examination (MMSE)]
4. Psychosis
5. Severe sight disorder or auditory defect
6. Alcohol-or drug abuse
7. Dementia (less than score 26 in MMSE)
8. Residence in institutions e.g. nursing homes or residential care home
9. Visits at the practice of the GP not possible, home visits required
10. Alcohol-or drug abuse
11. Participation in a clinical trial within the last 30 days

Date of first enrolment
01/05/2012

Date of final enrolment
30/04/2015

Locations

Countries of recruitment
Germany

Study participating centre
Johann Wolfgang Goethe University
Frankfurt
Germany
60590

Sponsor information

Organisation
Federal Ministry of Education and Research (Germany)

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Sponsor type
Government

Website
http://www.bmbf.de/foerderungen/14194.php

ROR
https://ror.org/04pz7b180

Funder(s)

Funder type
Government

Funder Name
Federal Ministry of Education and Research (Germany) ref: 01GY1145

Alternative Name(s)
Federal Ministry of Education and Research, BMBF

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Germany

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	25/10/2014		Yes	No
Results article	results	07/02/2017		Yes	No
Results article	results	01/08/2019	05/08/2019	Yes	No
Results article	results	16/03/2020	24/06/2020	Yes	No