ISRCTN44478543 https://doi.org/10.1186/ISRCTN44478543

Cardiovascular Risk Intervention Study to Optimise Treatment in Patients with Hypertension

Submission date
15/02/2006

Recruitment status
No longer recruiting

Registration date
12/06/2006

Overall study status
Completed

Last Edited
08/05/2015

Condition category
Circulatory System

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
01GL0501

Study information

Scientific Title

Cardiovascular Risk Intervention Study to Optimise Treatment in Patients with Hypertension

Acronym
CRISTOPH

Study objectives
As of 21/07/2008, the following amendments have been made to this ISRCTN record:
1. The end date of this trial was updated from 31/01/2007 to 31/12/2007. This reflects a delay to this trial due to several factors, mostly related to data collection
2. An amendment has been made to the Primary outcome measures field, as some errors were found in the information provided at time of registration

Hypothesis:
Absolute cardiovascular risk (CVR), calculated using the SCORE-formula (Conroy et al., European Heart Journal 2003; http://www.ncbi.nlm.nih.gov/pubmed/12788299), can be significantly decreased in patients with high CVR by means of a composed intervention, targeted at general practitioners, of posting specifically adapted guidelines and two educational outreach peer-visits (group A), compared with posting adapted guidelines alone (group B = control).

An embedded qualitative study (semi-structured interviews with general practitioners) focuses on the main reasons for physicians' non-compliance with guidelines in the German context.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Medical Faculty, University of Düsseldorf, 02/12/2005, ref: 2715

Study design
Cluster-randomised controlled two-arm interventional study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Increased cardiovascular risk

Interventions
This is a cluster-randomised controlled two-arm interventional study with an embedded qualitative study. A cluster is composed of the recruited patients of one GP surgery; in group practices, all GP partners are allocated to the same study arm.

Both groups A and B (the control arm) will receive specifically composed information by post, based on current guidelines on cardiovascular disease prevention.
In addition, group A will receive two educational outreach peer-visits, directed at a deeper appreciation of the concept of treating patients according to individual absolute cardiovascular risk.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Current primary outcome measures as of 21/07/2008:
Primary endpoint is the mean absolute cardiovascular risk (CVR) of the subset of patients with high CVR (but no manifest cardiovascular disease) in each randomisation group (A versus B). The composite endpoint 'cardiovascular risk' is calculated from several risk factors by using a slightly modified version of the SCORE formula published by Conroy et al. (European Heart Journal 2003).

Previous primary outcome measures:
Primary endpoint is the mean absolute cardiovascular risk (CVR) of the patients in each group. The composed endpoint cardiovascular risk is calculated from the single given risk factors by using a slightly modified version of the SCORE-formula published by Conroy et al. (European Heart Journal 2003).

For the qualitative study: adapting existing guideline tools for physicians' compliance.

Key secondary outcome(s))
1. The intervention's effect on blood pressure, cholesterol levels, smoking rates, and physical exercise in patients with:
a. A history of manifested CV disease
b. High CVR (defined by SCORE >4%)
c. Low CVR (SCORE <5%)

2. The intervention's effect on drug treatment, judged by current guidelines, in patients with:
a. A history of manifested CV disease
b. High CVR
c. Low CVR

3. A possible relationship of CVR with:
a. Patient gender
b. Patients' socioeconomic status
c. The quality of the doctor-patient-relationship

4. The intervention's effect on:
a. The accuracy with which doctors and patients estimate individual CVR
b. The degree to which the patient is being involved in the decision making process

Completion date
31/12/2007

Eligibility

Key inclusion criteria
102 general practitioners will be recruited to participate in the study, and will be randomised into groups A or B. Each GP recruits a consecutive sample of 40 patients meeting the following

criteria:
1. Aged 40-75 years
2. Known diagnosis of hypertension for >6 months
3. Life expectancy not <1 year
4. Fluency in the German language

The sample for the qualitative part covers 30 general practitioners not belonging to the quantitative study sample within the same region before the study and 15 general practitioners within the RCT-sample after the quantitative study.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Exclusion criteria for GPs are:
1. Less than 500 cases per three months (quarter)
2. Atypical patients or practice

Exclusion criteria for patients: see inclusion criteria

Date of first enrolment
01/03/2006

Date of final enrolment
31/12/2007

Locations

Countries of recruitment
Germany

Study participating centre
Abteilung für Allgemeinmedizin
Düsseldorf
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Sponsor information

Organisation
German Federal Ministry of Education and Research (BMBF) and the Federation of Sickness Fund Boards

ROR
https://ror.org/04pz7b180

Funder(s)

Funder type
Government

Funder Name
German Federal Ministry of Education and Research (Bundesministerium für Bildung und Forschung [BMBF])

Funder Name
Federation of Sickness Fund Boards (Spitzenverbände der Gesetzlichen Krankenkassen)

Results and Publications

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	07/05/2015		Yes	No
Protocol article	protocol	10/06/2008		Yes	No