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Implementation of Individualized Medicine: Education, Prediction and Treatment

Submission date
16/08/2013

Recruitment status
No longer recruiting

Registration date
15/04/2014

Overall study status
Completed

Last Edited
12/08/2020

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Effective treatment of hypertension is an important part of preventing many cardiovascular diseases. For a treatment to work, patients must take their medicines (medication adherence). Information about personal genetic risks gives patients the opportunity to consciously participate in the decision making process regarding the treatment, including decisions that ensure compliance.
The Estonian Genome Center, University of Tartu (EGCUT) is ready to provide doctors and patients with information on personal genetic risks of cardiovascular diseases but it is essential to study the effect of providing individual genetic feedback on medication adherence, health behaviour and treatment effectiveness for hypertension. There has been little research on the association between the feedback on personal genetic risks and medication adherence. The aim of the study is to assess whether it is acceptable to provide and receive genetic feedback so as to develop relevant marketing strategies for the service. It will be an opportunity to raise awareness of personalised medicine among the Estonian medical community and patients and to contribute to the international scientific debate on personalised medicine.

Who can participate?
Male between 18 and 65 years old, who are newly diagnosed with hypertension and are starting with medication treatment for hypertension.

What does the study involve?
The participants are recruited by their doctor. Once participants have signed the consent to participate they will be observed over a 12 month period. There are five study visits: Visit 1 (0 moment), Visit 2 (1.5 months after Visit 1), Visit 3 (3.5 months after Visit 1), Visit 4 (6 months after Visit 1), Visit 5 (12 months after Visit 1). Participants are randomly allocated to one of two groups: an intervention group or a control group. For the intervention group, the doctor shall provide individual feedback on genetic risks for diseases related to hypertension at the beginning of the study (during Visit 2). For the control group, the doctor shall provide with individual feedback about genetic risks at the end of the study (during Visit 4). The effect of the genetic feedback provided on the participants medication adherence and health behaviour will be studied.

What are the possible benefits and risks of participating?
Benefits - All participants receive genetic risk predictions for four conditions associated with hypertension. The timing of providing genetic information will differ between the control group and the intervention group. The choice of medication will not be affected by participation in the study. All the data of the participants is strictly confidential.
Risks - A blood sample of 10ml will be drawn from the participants for the genetic analysis. Such a small sample will not cause any harm to the participant. Blood tests can cause a bruise and leave a mark for a short period of time.

Where is the study run from?
The participants will be recruited at family practices in Tallinn and Tartu, and at the cardiologist walk-in clinic of East-Tallinn Central Hospital. Genetic analyses will be carried out at the Estonian Genome Center of the University of Tartu (Estonia).

When is the study starting and how long is it expected to run for?
August 2013 to August 2015.

Who is funding the study?
Archimedes Foundation (Estonia)

Who is the main contact?
Helene Alavere, project manager
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Open randomised controlled prevention trial to investigate the association between providing individual genetic risks for complications and medication adherence and treatment effectiveness of 1865-year-old men with hypertension in medical centres of Tartu and Tallinn in Estonia.

Acronym
IndiMed

Study objectives
The general objective of the study is to evaluate the applicability of personalised medicine (providing individual feedback about genetic risks) in ambulatory medical practice of hypertension.
Sub-objectives are to evaluate the effect of providing individual feedback about genetic risks on medication adherence (the primary outcome); and to evaluate the effect of providing individual feedback about genetic risks on treatment effectiveness of hypertension and health behaviour (the secondary outcomes).
An additional objective is to describe the acceptability of implementing individual feedback about genetic risks in medical practice by physicians as well as by patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Committee of the University of Tartu, 06/05/2013, ref 225/T-5

Study design
Multicentre open randomised controlled prevention trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Prevention

Participant information sheet
Not available in web format, please contact helene.alavere@ut.ee to request a patient information sheet [available in Estonian and Russian only]

Health condition(s) or problem(s) studied
Newly diagnosed hypertension encoded I10 (hypertension i.e. essential or primary arterial hypertension i.e. high blood pressure) or I11.9 (hypertensive heart disease with no (congestive) heart failure).

Interventions
At the early stages of medication treatment of hypertension, the physician shall be provided with the information regarding individual genetic risk of complications together with the standardised feedback about the non-genetic risks of complications.
Intervention Group: the physician shall provide genetic risk information to the participant at the beginning of the study (during Visit 2)
Control Group: the physician shall not provide genetic risk information to the participant before the end of the study (during Visit 4)
Total duration of follow-up is 5 visits to the general practitioner over a 12 month period.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Questionnaires used for hypertension treatment adherence assessment include :
1. Medication adherence (MMAS-8 and BMQ) is measured at 1.5 months, 3.5 months, 6 months and 12 months. MMAS-8 medication adherence questionnaire is comprised of 8 questions, the first seven of which can be answered with yes/no (yes=1 and no=0). The answers for the last question will give correspondingly 4, 3, 2, 1, or 0 points. The points are added and the medication adherence of the subject is evaluated according to the amount of points (8=good medication adherence, 6-7 average medication adherence, and less than 6 poor medication adherence). The score of medication adherence is calculated in the Estonian Genome Center of the University of Tartu (EGCUT).
For evaluating the BMQ questionnaire, there is a special table (presented by the author Bonni Svarstad), where treatment regimen adherence, occurrence of medication-related problems, and medication adherence related to forgetting and the availability of the medication are separately evaluated. The medication adherence rates are calculated by adding together the answers (yes=1 and no=0). The score of medication adherence is calculated in the EGCUT.
2. Registering medications prescribed and purchased at 1.5 months, 3.5 months, 6 months and 12 months. Registering medications prescribed and purchased according to the data in the Digital Prescription Center's digital prescription database, the data collector shall write them down into the corresponding form in the study folder.
3. Measuring and recording subjects' blood pressure and weight at baseline, 1.5 months, 3.5 months, 6 months and 12 months. The data collector shall measure the subject's blood pressure, body length, weight, waist and hip measurements (to evaluate the effectiveness of non-medication treatment) in a conventional way with devices that are in his/her possession, it is preferable to measure the subject with the same device, in the same conditions (measurements shall be taken standing up, body length without footwear, weight in similar clothing), and with the same methodology throughout the study.
4. Measuring and recording subjects' waist and hip measurements at baseline, 6 months , 12 months.

Secondary outcome measures
1. Measuring of blood pressure at baseline, 1.5 months, 3.5 months, 6 months and 12 months. Treatment effectiveness of hypertension: drop in systolic and diastolic blood pressure.
2. Smoking history recorded at baseline, 3.5 months, 6 months. Non-medication treatment adherence of hypertension (lifestyle recommendations) in subgroups (smokers, overweight individuals).

Overall study start date
31/08/2013

Completion date
31/08/2015

Eligibility

Key inclusion criteria
Male, 18 to 65 years of age, who is subject to one of the followings:
1. Newly diagnosed hypertension* encoded** I10 [hypertension i.e. essential or primary arterial hypertension i.e. high blood pressure) or I11.9 (hypertensive heart disease with no (congestive) heart failure] or previously diagnosed hypertension encoded I10 or I11.9, with no medication treatment receive or previously diagnosed hypertension encoded I10 or I11.9 with assigned medication treatment that has been discontinued at least two months ago
* mean arterial blood pressure of three measurements: systolic over 140; and/or diastolic over 90 mmHg
** here and hereinafter the diagnosis codes are presented according to the 10th revision of the International Classification of Diseases
The patient shall (re)start the medication treatment of hypertension according to the physicians assessment
2. ECG findings: sinus rhythm, without signs of having suffered from myocardial infraction and /or of acute ischemia
3. Gives an informed consent to participate in the study
4. The subject is prepared to find out his genetic risks

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Male

Target number of participants
300 in total, with 150 in the intervention group and 150 in the control group

Key exclusion criteria
Physical or psychological comorbidities/conditions or their treatment which, according to the attending physician's assessment, may prevent or significantly affect:
1. Giving the informed consent
2. Participating in the study
3. The mean arterial blood pressure of three measurements during Visit 1: systolic over 180; and /or diastolic over 110 mmHg

Date of first enrolment

31/08/2013

Date of final enrolment
31/08/2015

Locations

Countries of recruitment
Estonia

Study participating centre
Riia 23b, 51010 Tartu
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Sponsor information

Organisation
Archimedes Foundation (Estonia)

Sponsor details
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Sponsor type
Government

Website
http://archimedes.ee/en/foundation/

ROR
https://ror.org/02pagex14

Funder(s)

Funder type
Government

Funder Name
The project is funded by structural assistance in the sub-measure of the Operational Programme for the Development of Economic Environment titled Aid for research and development in health care, application: Implementation of Individualized Medicine: Education, Prediction and Treatment (IndiMed), reference number 3.2.1001.11-0033

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