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Abdominal aortic aneurysm screening by ultrasonography in primary care

Submission date
27/02/2015

Recruitment status
No longer recruiting

Registration date
30/03/2015

Overall study status
Completed

Last Edited
09/10/2015

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
The aorta is a blood vessel that is responsible for transporting blood from the heart to other organs. The abdominal aortic aneurysm is a dilation of the aorta in the abdominal region. It can occur in any person, but is more common in men over 60 who smoke, have high blood pressure or have a close relative that has the condition. The abdominal aortic aneurysm affects 4-8% of men over 65 years, the risk increasing with smoking and age. This disease develops slowly over many years and most cases are asymptomatic. However, if an aneurysm expands rapidly, or breaks, it becomes a true medical emergency with a high death rate. It is hypothesised that early detection of AAA will decrease all-cause death rates by 2% and the need for emergency surgery by 50%. Here, we will test abdominal ultrasound as a diagnostic tool for AAA. We will also study the risk factors of the disease.

Who can participate?
Men aged between 65-74 years living in Vigo (Spain)

What does the study involve?
Participants are recruited from a list of medical records. They are chosen at random to be invited to take an active part in the study or become part of the control group. The active participants first undergo an initial consultation. This takes about 30 minutes, and includes going through the participants background medical history. An abdominal ultrasound is then performed. This takes about 15 minutes. Most men are expected to have a normal result, which makes it very unlikely that they will develop an aneurysm later. In the event that an aneurysm of > 3 cm is detected, the participant is referred to a vascular surgeon, for further testing. It is expected that only for 1-2 out of 100 participants in the study will fall into this category. Participants with small or slow-growing aneurysms are followed by the family doctor regularly to make recommendations or treatment as needed. For patients that are diagnosed with a larger aneurysm, there is a referral to a surgeon. Depending on the size and evolution of the aneurysm, surgical treatment may be necessary. Participants in the control group are followed anonymously from from the administrative databases of SERGAS for the duration of the study.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
EOXI Vigo (Spain)

When is the study starting and how long is it expected to run for?
January 2014 to January 2021

Who is funding the study?
Spanish Research Network

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Abdominal aortic aneurysm screening by ultrasonography in primary care: a community screening trial

Acronym
ECOAAA

Study objectives
The expected prevalence for this age-sex cohort is 4 to 8%. Conducting an ultrasound screening in primary care of male patients aged 65 to 74 years, will detect at least 40 asymptomatic patients with abdominal aortic aneurysm (AAA). The risk factors most closely associated with AAA are cardiovascular disease and smoking. Early detection of AAA will decrease all-cause mortality by 2% and emergency surgery for AAA by 50%.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Galician Ethics Committee (Spain), 12/12/2013, ref: 2013/532.

Study design
Pragmatic community screening trial.

Primary study design
Interventional

Secondary study design
Pragmatic randomized trial

Study setting(s)
GP practice

Study type(s)
Screening

Participant information sheet
Not available in web format, please use contact details to request a patient information sheet.

Health condition(s) or problem(s) studied
Abdominal aortic aneurysm (AAA)

Interventions
Intervention cohort: all men aged 65 to 74, attended by each of family physician (FP) researchers.

Recruitment: Each FP researcher (clinical group) provides a list of patients in the age and sex group to the methodological research team group. The administrative area of the health center and / or health care professional project support sent a letter signed by the family physician informing the patient of the study and requesting their participation invitation. Electronic medical records will be reviewed in collaboration with the Teaching Unit of Family and

Community Medicine of Vigo and practitioners themselves. Patients will be referred for ultrasound and consultation with their FP. Those who do not answer after a second contact by mail will be considered losses (age, sex and health center shall be recorded).

First consultation: The FP conducted the initial consultation, including informing the patient and answering questions, written informed consent by the patient, filling webpage data collection with the variables included in the study, conduct ultrasound scans and previews that are not recorded in the electronic medical record (EMR) and quote for analytical extraction if it lacks in the previous 6 months. The results will be communicated to the patient and the treatment of their disease and / or risk factors will be adjusted according to clinical guidelines.

To visualize the aorta, the transducer is placed longitudinally just above and slightly to the left of the umbilicus. The maximum transverse diameter in the transverse plane and the anterior-posterior diameter maximum in the longitudinal direction will be measured. Two readings are made and the highest value is registered in. The researcher recorded the data of the patients included in the study in an electronic linked to a web page created for this purpose. This NDC contains software filters that act as a first quality control of recorded data. It was also recorded in the EMR in a note associated with existing or new episode of vascular pathology or an episode of preventive activities (if it had pathology). Monitoring in patients with AAA will be performed depending on the size of the aneurysm. Criteria for referral will be reviewed with the services involved Vascular Surgery and Cardiology (Vigo University Hospital Complex and POVISA) following the recommendations of the European Society for Vascular Surgery. Reassessment of those AAA diameters less than 3.0 cm is not required. Those under 4cm shall be reassessed annually by the FP. Those over 4cm be reassessed will be forwarded to vascular surgery. Those from 4-4.9cm can opt between immediate repair and delayed repair. Surgical repair is recommended when the size exceeds 5-5.5 cm. This will be a shared decision by vascular surgeons and patients, weighing the risks of rupture and surgery.

AAA is expected to be ruled out in 1.2% of patients. These will be assessed by complementary image diagnosis (estimated: 10-15). In parallel, participants will be treated in primary care for monitoring risk factors and / or other pathologies as clinical guidelines, with particular emphasis on prevention / treatment of smoking and hypertension.

Intervention Type
Mixed

Primary outcome measure
At 31/12/2020, the impact of early diagnosis in reducing overall mortality, cardiovascular mortality and incidental AAA will be evaluated. To this end, information will be requested relative to the intervention and control cohorts from the Death Registry and at the Galician Health Service: Deaths (by all causes and by cardiovascular causes) and patients detected by incidental hospital diagnosis (hospitalisation and/or emergency surgery for AAA). The specific mortality due to AAA will not be considered due to its low sensitivity.

Secondary outcome measures
1. Cardiovascular mortality
2. Surgery for AAA (type of surgery, scheduled/emergency)
3. Type of discharge from hospital

Overall study start date
01/01/2014

Completion date
01/01/2021

Eligibility

Key inclusion criteria
The setting will be the Integrated Management Area of Vigo, which has 583,124 habitants, 23 PC departments and 42 health centres. 21 family doctors (FD) belonging to 14 PC departments in the Vigo area, trained in abdominal ultrasonography and with ultrasound equipment at their health centre, will form the research team's clinical group. The availability of ultrasound equipment in the centres is part of the portfolio of primary care services of the Vigo area (equipment that is currently available in 11 of the 23 PC departments) and was selected based on the specific training in ultrasonography of any of the family doctors of this centre and their availability to undertake this activity for the whole team.

Intervention cohort:
1. Men aged 65 to 74 years The participating patients will sign the informed consent to participate in the study. Patients who choose not to participate or who do not sign the informed consent will be considered losses. The exclusion criteria refer exclusively to age and sex, bedridden/immobilised patients or those with a previously diagnosed aneurysm.

2. The control cohort will consist of patients of the same sex and age belonging to the remaining quotas of the Vigo area. The patients' data will be extracted anonymously from the administrative databases of SERGAS and therefore do not require informed consent.

Participant type(s)
Patient

Age group
Senior

Sex
Male

Target number of participants
837 in the intervention group and 2511 in control group.

Key exclusion criteria
1. Women
2. <65 or >74
3. Terminally ill
4. Immobilized
5. Previous AAA diagnosed or repaired.

Date of first enrolment
01/01/2015

Date of final enrolment
31/12/2020

Locations

Countries of recruitment
Spain

Study participating centre
EOXI Vigo
EOXI Vigo
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Sponsor information

Organisation
EOXI Vigo

Sponsor details
Vigo
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Spain
36201

Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Research organisation

Funder Name
Red Española de Atención Primaria (Spanish Research Network)

Results and Publications

Publication and dissemination plan

Study protocol to be published in BMC Family Practice. Basal data in next year. Final data in five years.

Intention to publish date
30/06/2015

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request