ISRCTN04011070 https://doi.org/10.1186/ISRCTN04011070

Targeted screening for ovarian cancer in women over 50 years of age with vague presenting symptoms

Submission date
12/09/2003

Registration date
12/09/2003

Last Edited
24/05/2012

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Cancer

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

Plain English summary of protocol
http://cancerhelp.cancerresearchuk.org/trials/a-study-looking-at-screening-the-general-population-for-ovarian-cancer

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N0205116658

Study information

Scientific Title

Study objectives
Ovarian cancer (OC) is the most common gynaecological malignancy in the UK and carries the highest mortality rate. This is believed to be due to the majority of women presenting with late stage disease. The small proportion of women who are diagnosed at an early stage have a significantly improved prognosis, suggesting that diagnosis at an earlier stage may result in a significant improval in survival.

Contrary to widely held views that ovarian cancer is asymptomatic until it reaches a late stage, retrospective studies, based on review of patient notes, suggest that most women diagnosed with OC do report symptoms, although these are usually not gynaecological in nature. These symptoms are mainly vague in nature. The most common symptoms were: increased abdominal size, abdominal bloating, fatigue, abdominal pain, indigestion and urinary frequency. Women also complain of delay in diagnosis due to factors such as incorrect initial diagnosis, initial referral to the wrong specialist, omission of a pelvic examination at the first visit, and not receiving an early ultrasound or CA125 test. The present Cancer Collaborative guidelines for urgent referral do not address the fact that most women present with vague, non gynaecological symptoms.

This study is designed to ascertain whether screening women with vague symptoms, and educating GPs about ovarian cancer symptoms, alters time to diagnosis and stage distribution of OC.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Screening

Health condition(s) or problem(s) studied
Ovarian cancer

Interventions
All the general practices in the ELCHA region will be randomised. No contact will be made with the GPs randomised to the control group. Those practices randomised to the study group will be contacted to inform them about the study and invite their participation. GPs in this group will be asked to refer women, over 50 years of age and presenting with non-specific symptoms, and no obvious diagnosis, for a transvaginal ultrasound scan (TVS) and CA125 test. CA125 and TVS are considered the standard diagnostic tools for suspected ovarian cancer. Those women referred to the gynaecology cancer centre from the study group, and those referred in the usual way, with ovarian cancer, will be asked to fill in a questionnaire related to symptoms and patient satisfaction. The primary analysis will be of time from presentation to diagnosis of women with ovarian cancer in the control group compared to the study group. No data have been published

on time to referral in ovarian cancer. There is some limited retrospective data from the USA on the interval from time of presentation to diagnosis.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
The primary analysis will be of time from presentation to diagnosis of women with ovarian cancer in the control group compared to the study group.

Key secondary outcome(s))
Not provided at time of registration

Completion date
01/12/2005

Eligibility

Key inclusion criteria
All general practices in East London and The City Health Authority (ELCHA) will be randomised to the study and control groups. We will follow up all ovarian cancers from both groups.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/07/2002

Date of final enrolment
01/12/2005

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
Gynaecological Research Unit
London
United Kingdom
EC1M 6GR

Sponsor information

Organisation
Department of Health (UK)

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Barts and The London NHS Trust (UK)

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	01/01/2007		Yes	No