

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

Submission date 12/09/2003	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/09/2003	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 24/05/2012	Condition category Cancer	<input type="checkbox"/> 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

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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 improvement 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

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Screening

Participant information sheet

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

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 measure

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.

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/07/2002

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

Age group

Adult

Sex

Female

Target number of participants

Not provided at time of registration

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**

England

United Kingdom

Study participating centre

Gynaecological Research Unit

London

United Kingdom

EC1M 6GR

Sponsor information**Organisation**

Department of Health (UK)

Sponsor details

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

Sponsor type

Government

Website

<http://www.doh.gov.uk>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Barts and The London NHS Trust (UK)

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	01/01/2007		Yes	No