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Cancer Loyalty Card Study (CLOCS): aiming to reduce delays in cancer diagnosis using everyday data

Submission date
16/09/2019

Recruitment status
No longer recruiting

Registration date
29/10/2019

Overall study status
Completed

Last Edited
19/12/2024

Condition category
Cancer

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

Plain English summary of protocol

https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-at-how-women-manage-symptoms-that-might-be-ovarian-cancer-cancer-loyalty-card-study

Background and study aims
The Cancer Loyalty Card Study (CLOCS) is addressing whether data already collected by high street retailers can detect significant changes in purchase behaviours of ovarian cancer patients prior to their diagnosis. The researchers aim to conduct a study of ovarian cancer patients matched with women who do not have ovarian cancer and collate up to 7 years of prior purchase data.

Who can participate?
Ovarian cancer patients aged 18 and older with loyalty cards at a participating high street retailer and women aged 18 and older who have not been diagnosed with ovarian cancer

What does the study involve?
Consenting participants provide their loyalty card details and complete a brief questionnaire about ovarian cancer risk factors, which is also returned to the CLOCS team through the mail or on the secure website (healthy volunteers only). Participants with ovarian cancer also have a clinical form for a member of their clinical team to complete in the clinic. This is sent to the CLOCS team along with their consent and risk factor questionnaire in a freepost envelope. If participants consent to be re-contacted by the CLOCS team for future studies or for loyalty card detail clarification, they provide either a contact email or phone number. There is no further action needed from participants once they complete and return their consent form and questionnaire (and clarify loyalty card details if necessary).

What are the possible benefits and risks of participating?
There are no clear risks in taking part in this study. However, it may be emotional or distressing to think about cancer and the first time a patient noticed some changes in their body. The researchers intended to design the survey questions in the most sensible and sensitive way to ensure that there are no negative effects of this study on patients' well-being. To their

knowledge, this study is a unique project which could have important public health benefits for women. If the study is successful, this could be instrumental in raising cancer symptom awareness in commercial settings.

Where is the study run from?
Imperial College London (UK)

When is the study starting and how long is it expected to run for?
February 2019 to July 2022

Who is funding the study?
Cancer Research UK

Who is the main contact?
Dr James Flanagan, j.flanagan@imperial.ac.uk

Study website
https://www.clocsproject.org.uk/

Contact information

Type(s)
Scientific

Contact name
Dr James Flanagan

Contact details
Imperial College London
Division of Cancer, Department of Surgery and Cancer
Hammersmith Campus
Du Cane Road (Artillery Lane)
London
United Kingdom
W12 0HS
+44 (0)207 5942127
j.flanagan@imperial.ac.uk

Type(s)
Scientific

Contact name
Dr Hannah Brewer

Contact details
Imperial College London
4th Floor, Institute of Reproductive and Developmental Biology (IRDB)
London
United Kingdom

W12 0HS
+44 (0)7503468620
h.brewer@imperial.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
262776

ClinicalTrials.gov number
NCT03994653

Secondary identifying numbers
CPMS 43323

Study information

Scientific Title
Cancer Loyalty Card Study (CLOCS)

Acronym
CLOCS

Study objectives
Approximately 7,400 new cases of ovarian cancer are diagnosed each year in the United Kingdom, and with over 4,000 women dying from the disease each year it is a particularly lethal form of cancer. The symptoms for ovarian cancer are not well known and vague, and most women are diagnosed at a late stage when the cancer has already spread around the abdominal cavity with poor prognosis. Novel methods are needed to improve earlier detection and thereby improve survival from this disease.

In the Cancer Loyalty Card Study (CLOCS) the researchers propose to use loyalty card data from two participating high street retailers to investigate purchase behaviour as an opportunity for cancer symptom surveillance. They aim to conduct a case-control study of ovarian cancer patients matched with women without ovarian cancer and to explore public preferences for how to communicate potential outcomes of the commercial and health data linkages back to individuals.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/09/2019, North West - Greater Manchester South Research Ethics Committee (3rd Floor, Barlow House 4 Minshull Street Manchester M1 3DZ, UK; Tel: +44 (0)207 104 8010; Email: nrescommittee.northwest-gmsouth@nhs.net), REC ref: 19/NW/0427

Study design

Observational; Design type: Case-controlled study

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
Community, Retail/food outlet

Study type(s)
Other

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

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

Interventions
Eligible participants will be women in the UK who own at least one loyalty card with the participating high street retailers. Of these women, those who have been diagnosed with ovarian cancer are eligible to participate in the study as cases, while women who have not been diagnosed with ovarian cancer are eligible to participate as controls.

Upon choosing to participate, all participants will be asked to complete a short questionnaire about well-established ovarian cancer risk factors and common symptoms either in the clinic (cases) or online/from a packet in the mail (controls). This information will be used in risk assessment for ovarian cancer of participants, which will be used at the analysis stage.

Once participant questionnaires and consent forms are returned to the CLOCS research team, only the researchers will have access to participants' past purchase information already collected by high street retailers through the use of loyalty cards.

Intervention Type
Other

Primary outcome measure
The time by which the cases and controls are statistically significantly different in their purchase behaviours leading up to diagnosis on a population level. Method: Data will be collected using questionnaire to establish ovarian cancer risk factors and clinical information; high street retailer loyalty cards data will be collected to establish an individual's purchases and purchase behaviours. Timepoints: Participants will be recruited at baseline, and data collected at one timepoint (date of recruitment), and all data available up until that timepoint will be analysed.

Secondary outcome measures
The purchase threshold defined as an "alert" about cancer symptoms in individuals and the predictive utility of purchasing behaviours in the early detection of ovarian cancer. Exploratory analyses will include longitudinal analyses, frequency of purchases and unbiased analysis of

other purchase categories. Method: Data will be collected using questionnaire to establish ovarian cancer risk factors and clinical information; high street retailer loyalty cards data will be collected to establish an individual's purchases and purchase behaviours; Timepoints: Participants will be recruited at baseline, and data collected at one timepoint (date of recruitment), and all data available up until that timepoint will be analysed.

Overall study start date
01/02/2019

Completion date
31/07/2022

Eligibility

Key inclusion criteria
1. Women, at least 18 years old, recently diagnosed with ovarian cancer (preferably recruited just after diagnosis and during treatment period, but are still eligible if diagnosed up to 2 years prior, at the latest) who hold at least one participating high street retailer loyalty card are eligible to join the CLOCS as cases
2. Women, at least 18 years old, who have not been diagnosed with ovarian cancer and hold at least one participating high street retailer loyalty card are eligible to join the CLOCS as controls

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
Planned Sample Size: 1000; UK Sample Size: 1000

Total final enrolment
624

Key exclusion criteria
1. Women under the age of 18 years
2. Men

Date of first enrolment
01/11/2019

Date of final enrolment
28/07/2022

Locations

Countries of recruitment
England

Scotland

United Kingdom

Wales

Study participating centre
Imperial College London
Department of Surgery and Cancer
Du Cane Road (Artillery Lane)
London
United Kingdom
W12 0HS

Study participating centre
Imperial College Healthcare NHS Trust
St Marys Hospital
Praed Street
London
United Kingdom
W2 1NY

Study participating centre
Sandwell and West Birmingham Hospitals NHS Trust
City Hospital
Dudley Road
Birmingham
United Kingdom
B18 7QH

Study participating centre
University College London Hospitals NHS Foundation Trust
250 Euston Road
London
United Kingdom
NW1 2PG

Study participating centre
County Durham and Darlington NHS Foundation Trust
Darlington Memorial Hospital
Hollyhurst Road
Darlington
United Kingdom
DL3 6HX

Study participating centre
Walsall Healthcare NHS Trust
Manor Hospital
Moat Road
Walsall
United Kingdom
WS2 9PS

Study participating centre
Surrey and Sussex Healthcare NHS Trust
East Surrey Hospital
Canada Avenue
Redhill
United Kingdom
RH1 5RH

Study participating centre
Airedale NHS Foundation Trust
Airedale General Hospital
Skipton Road
Steeton
Keighley
United Kingdom
BD20 6TD

Study participating centre
Abertawe Bro Morgannwg University LHB
One Talbot Gateway, Seaway Drive
Seaway Parade Industrial Estate
Baglan
Port Talbot
United Kingdom
SA12 7BR

Study participating centre
Gateshead Health NHS Foundation Trust
Queen Elizabeth Hospital
Gateshead
United Kingdom
NE9 6SX

Study participating centre
Norfolk and Norwich University Hospitals NHS Foundation Trust
Colney Lane
Colney
Norwich
United Kingdom
NR4 7UY

Study participating centre
Leeds Teaching Hospitals NHS Trust
St. James's University Hospital
Beckett Street
Leeds
United Kingdom
LS9 7TF

Study participating centre
NHS Lothian
Waverley Gate
2-4 Waterloo Place
Edinburgh
United Kingdom
EH1 3EG

Study participating centre
East Lancashire Hospitals NHS Trust
Royal Blackburn Hospital
Haslingden Road
Blackburn
United Kingdom
BB2 3HH

Study participating centre

University Hospitals Bristol NHS Foundation Trust
Marlborough Street
Bristol
United Kingdom
BS1 3NU

Study participating centre
Royal Surrey County Hospital NHS Foundation Trust
Egerton Road
Guildford
United Kingdom
GU2 7XX

Study participating centre
The Royal Marsden NHS Foundation Trust
Fulham Road
London
United Kingdom
SW3 6JJ

Study participating centre
Velindre NHS Trust
Unit 2
Charnwood Court
Heol Billingsley
Cardiff
United Kingdom
CF15 7QZ

Study participating centre
Cardiff & Vale University LHB
Corporate Headquarters
Heath Park
Cardiff
United Kingdom
CF14 4XW

Study participating centre
South Tees Hospitals NHS Foundation Trust
James Cook University Hospital
Marton Road

Middlesbrough
United Kingdom
TS4 3BW

Study participating centre
West Hertfordshire Hospitals NHS Trust
Trust Offices
Watford General Hospital
Vicarage Road
Watford
United Kingdom
WD18 0HB

Study participating centre
The Christie NHS Foundation Trust
550 Wilmslow Road
Withington
Manchester
United Kingdom
M20 4BX

Study participating centre
Manchester University NHS Foundation Trust
Cobbett House
Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre
NHS Greater Glasgow and Clyde
J B Russell House
Gartnavel Royal Hospital
1055 Great Western Road
Glasgow
United Kingdom
G12 0XH

Sponsor information

Organisation
Imperial College of Science, Technology and Medicine

Sponsor details
c/o Becky Ward
215, 2nd Floor, Norfolk Place
St Mary's Campus
London
England
United Kingdom
W2 1PG
+44 (0)20 7594 9459
becky.ward@imperial.ac.uk

Sponsor type
University/education

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK; Grant Codes: C38463/A26726

Alternative Name(s)
CR_UK, Cancer Research UK - London, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan

1. Peer reviewed scientific journals
2. Conference presentation
3. Publication on website

Intention to publish date
30/06/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to fact that the raw data contains participant identifiable data and only the anonymised risk factor questionnaire data will be made available to collaborators upon reasonable request.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	08/09/2020	10/09/2020	Yes	No
Results article		26/01/2023	27/01/2023	Yes	No
Results article		14/06/2023	15/06/2023	Yes	No
HRA research summary			28/06/2023	No	No
Plain English results			10/04/2024	No	Yes