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Access to medications that reduce the risk of cancer in the NHS

Submission date
18/03/2016

Recruitment status
No longer recruiting

Registration date
21/03/2016

Overall study status
Completed

Last Edited
10/07/2018

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
Around four in 10 cases of cancer could be prevented in the UK, largely through lifestyle changes. In addition, chemoprevention – the use of cancer-preventing drugs – has the potential to save many lives by stopping cancer developing in the first place. Chemoprevention is a relatively new approach to cancer prevention and we know that there is considerable variability in the uptake of different medicines. In response, the Cancer Strategy for England recommends a more systematic approach to making chemoprevention available. Ensuring evidence-based chemoprevention is routinely discussed with and offered to the relevant people should be a priority across the UK. For example, an estimated quarter of a million women in the UK are at increased risk of breast cancer and are eligible for preventive medications. And research demonstrates that chemoprevention using Selective Oestrogen-Receptor Modulators (SERMs) such as tamoxifen and raloxifene can reduce incidence of breast cancer by around a third or more among women with a clear family history of the disease. However, it is not currently possible to understand on a national level what the level of uptake of chemoprevention currently is or how many cases of cancer could be prevented should uptake increase. Published studies suggest there may be problems with making chemoprevention part of routine clinical practice. The aim of this study is to examine if general practitioners (GPs) are willing to prescribe tamoxifen.

Who can participate?
GPs or trainee GPs who are based in the UK.

What does the study involve?
Participants are randomly allocated to read one of four stories about a 45 year old patient at increased risk of breast cancer and are told to imagine they are consulting with them .Those in the first group are told the patient is of moderate risk and they are the ones to prescribe them with a preventative medication. Those in the second group are told the patient is of high risk and they are the ones to prescribe them with a preventative medication. Those in the third group are told the patient is of moderate risk and they are the second prescriber of the preventative medication (the first prescriber is a secondary care clinician). Those in the fourth group are told the patient is of high risk and the GP is the second prescriber. Participants are measured to see if they are willing to prescribe tamoxifen to the patient.

What are the possible benefits and risks of participating?
There are no direct benefits of risks for those taking part in the study.

Where is the study run from?
Queen Mary University of London (UK)

When is the study starting and how long is it expected to run for?
February 2016 to September 2016

Who is funding the study?
Cancer Research UK (UK)

Who is the main contact?
Dr Samuel Smith
sam.smith@qmul.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Samuel Smith

ORCID ID
http://orcid.org/0000-0003-1983-4470

Contact details
Centre for Cancer Prevention
Queen Mary University of London
Wolfson Institute of Preventive Medicine
Charterhouse Square
London
United Kingdom
EC1M 6BQ
+44 (0)20 7882 5698
sam.smith@qmul.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
v1.0

Study information

Scientific Title
Access to chemoprevention in the NHS

Study objectives
H1. GPs will be more willing to prescribe tamoxifen if they are told the patient is at high risk of breast cancer compared with moderate risk of breast cancer
H2. GPs will be more willing to prescribe tamoxifen if they are told the family history clinician has written the first prescription, compared with GPs told they are requested to write the first prescription
H3. GPs will be more willing to prescribe tamoxifen if they are told the family history clinician has written the first prescription, and this effect will be greatest among those in the high risk compared with moderate risk scenario

Ethics approval required
Old ethics approval format

Ethics approval(s)
Queen Mary Ethics of Research Committee, 22/02/2016, ref: QMREC1481

Study design
Randomised 2 x 2 factorial design of a patient vignette

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Prescribing behaviour

Interventions
GPs will be randomised to read one of four vignettes describing a 45 year old patient at increased risk of breast cancer. The GPs are told to imagine the patient has consulted them and they have been referred to a family history clinic in secondary care. Two vignettes will describe the patient as having a high risk of breast cancer (≥30% lifetime risk), and two of the vignettes will describe her as having a moderate risk of breast cancer (17-30% lifetime risk). The vignette describes the hypothetical discussion that took place in secondary care, and suggests the patient is interested in taking tamoxifen for primary prevention purposes. Two of the vignettes request that the GP writes the first prescription for tamoxifen and continues to act as the main

prescriber. The remaining two vignettes describe a situation in which the secondary care clinician has written the first prescription, and the GP is being asked to take over as the main prescriber.

The GPs will be allocated randomly to one of the four scenarios:
1. Moderate risk patient and GP is the first prescriber
2. High risk patient and GP is the first prescriber
3. Moderate risk patient and GP is the second prescriber
4. High risk patient and GP is the second prescriber

Intervention Type
Behavioural

Primary outcome measure
The main effects of:
1. Risk level
2. First prescriber
on willingness to prescribe tamoxifen. This will be measured immediately after reading the vignette using the item: 'Would you be willing to write the prescription for [patient name]?', 'Not at all willing', 'probably not willing' 'probably willing' 'definitely willing'.

Secondary outcome measures
Current secondary outcome measures as of 15/09/2017:
All outcomes will be measured immediately after the GP has read the vignette.
1. Interaction between risk level and first prescriber on willingness to prescribe tamoxifen
2. Willingness to prescribe within pre-defined respondent groups:
2.1. Males vs. female GPs
2.2. GP specialist trainees vs. GP partners vs. Salaried GPs
2.3. Special interest in cancer/preventive medicine/family history/genetics vs. none of these
3. Wanting to speak with a colleague before writing the prescription ('Would you want to speak with anyone else before you decided whether to write this prescription?' 'yes' 'no')
4. Comfort in discussing the possible benefits and harms of tamoxifen ('How comfortable would you feel discussing the possible benefits and harms of tamoxifen with [patient name]?' 'very uncomfortable' 'quite uncomfortable' 'quite comfortable' 'very comfortable'
5. Comfort in managing the care of the patient ('If [patient name] started taking tamoxifen, how comfortable would you feel managing her care for the duration of the prescription?' 'very uncomfortable' 'quite uncomfortable' 'quite comfortable' 'very comfortable')
6. Factors considered during the decision-making process:
('How much do you agree or disagree that the following factors affected your decision of whether or not to write a prescription for [patient name]?' 'Strongly disagree' 'disagree' 'agree' 'strongly agree'
6.1. Evidence for the benefits of the drug
6.2. The evidence for the harms of the drug
6.3. Prescribing ‘off-label’
6.4. The first prescription being made by a family history clinician
6.5. The first prescription being made by the GP
6.6.The financial costs of tamoxifen
6.7. Patient risk level
6.8. Patient’s interest in taking tamoxifen
6.9. Patient’s awareness of the possible harms and benefits
6.10. GP’s confidence in knowledge of tamoxifen
6.11. Patient’s support from the genetics clinician

6.12. The attitudes of the GP's colleagues who are at the same career stage
6.13. The attitudes of the GP's colleagues who are more senior
6.14. The prescribing budget in the General Practice
6.15. The policy of the local Clinical Commissioning Group
6.16. The existence of NICE guidelines (or national equivalent)
6.17. Other
7. Free text comments at end of the survey

Previous secondary otucome measures:
All outcomes will be measured immediately after the GP has read the vignette.
1. Interaction between risk level and first prescriber on willingness to prescribe tamoxifen
2. Willingness to prescribe within pre-defined respondent groups:
2.1. Males vs. female GPs
2.2. GP specialist trainees vs. GP partners vs. Salaried GPs
2.3. Special interest in cancer/preventive medicine/family history/genetics vs. none of these
2.4. Deprived (quintiles 1-3) vs. non-deprived (quintiles 4-5) practices based on IMD score
3. Wanting to speak with a colleague before writing the prescription ('Would you want to speak with anyone else before you decided whether to write this prescription?' 'yes' 'no')
4. Comfort in discussing the possible benefits and harms of tamoxifen ('How comfortable would you feel discussing the possible benefits and harms of tamoxifen with [patient name]?' 'very uncomfortable' 'quite uncomfortable' 'quite comfortable' 'very comfortable'
5. Comfort in managing the care of the patient ('If [patient name] started taking tamoxifen, how comfortable would you feel managing her care for the duration of the prescription?' 'very uncomfortable' 'quite uncomfortable' 'quite comfortable' 'very comfortable')
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('How much do you agree or disagree that the following factors affected your decision of whether or not to write a prescription for [patient name]?' 'Strongly disagree' 'disagree' 'agree' 'strongly agree'
6.1. Evidence for the benefits of the drug
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6.14. The prescribing budget in the General Practice
6.15. The policy of the local Clinical Commissioning Group
6.16. The existence of NICE guidelines (or national equivalent)
6.17. Other
7. Free text comments at end of the survey

Overall study start date
18/02/2016

Completion date

30/09/2016

Eligibility

Key inclusion criteria
1. General practitioner (or GP specialist trainee)
2. Based in the UK

Participant type(s)
Health professional

Age group
Adult

Sex
Both

Target number of participants
1000

Key exclusion criteria
Not a General Practitioner

Date of first enrolment
28/03/2016

Date of final enrolment
29/04/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Queen Mary University of London
Centre for Cancer Prevention
Wolfson Institute of Preventive Medicine
Charterhouse Square
London
United Kingdom
EC1M 6BQ

Sponsor information

Organisation
Queen Mary University of London

Sponsor details
Mile End Road
London
England
United Kingdom
E1 4NS

Sponsor type
University/education

ROR
https://ror.org/026zzn846

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK

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
Publish main results in a 'white paper' on behalf of Cancer Research UK and in a scientific manuscript. The primary and secondary outcomes will be published in both publications.

Intention to publish date

01/01/2018

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository. The data are stored on a secure network available to the PI. The process for requesting access is by contacting the principal investigator who will assess the request and provide anonymised data once a data sharing agreement has been put in place. Consent from participants was obtained for participating in this research, but I am unaware in consent was secured for data sharing.

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2017		Yes	No