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eRAPID Electronic patient self-Reporting of Adverse-events: Patient Information and aDvice: randomised controlled trial in systemic cancer treatment

Submission date
11/09/2014

Recruitment status
No longer recruiting

Registration date
11/09/2014

Overall study status
Completed

Last Edited
11/01/2021

Condition category
Cancer

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

Plain English summary of protocol
http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-at-a-way-to-report-side-effects-of-treatment-online-from-home-erapid-rct

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
17000

Study information

Scientific Title
eRAPID Electronic patient self-Reporting of Adverse-events: Patient Information and aDvice: randomised controlled trial in systemic cancer treatment

Acronym
eRAPID RCT in systemic cancer treatment

Study objectives
eRAPID (electronic patient self-Reporting of Adverse-events: Patient Information and aDvice) is an online system for patients to self-report symptoms and side effects (known as adverse events or AE) during and after cancer treatments. eRAPID allows AE reporting from home or hospital and the patient reported data is integrated into existing Electronic Patient Records to allow for the reports to be used in routine care. In addition the system is capable of generating alerts for severe AE to the relevant clinical team and providing patient advice on managing mild AE.

The overall aims of the eRAPID system are to improve the safe delivery of cancer treatments, enhance patient care and standardise documentation of AE within the clinical datasets.

Ethics approval required
Old ethics approval format

Ethics approval(s)
14/YH/1066

Study design
Randomised; Interventional; Design type: Process of Care

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
Colorectal cancer, breast cancer, cervical cancer, ovarian cancer, rectal cancer or uterine cancer

Interventions
Participants allocated to the intervention arm will have access to the eRAPID online system for self-reporting symptoms and side effects/adverse events (AE) during systemic cancer treatment. eRAPID allows AE reporting from home or hospital and the patient reported data is integrated into existing Electronic Patient Records to allow for the reports to be used in routine care. In addition the system is capable of generating alerts for severe AE to the relevant clinical team.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Clinical outcomes and process of care measures; Timepoint(s): Throughout 18 week study period

Secondary outcome measures
1. Costs to patients and the NHS; Timepoint(s): Throughout 18 week study period
2. Patient-reported outcomes; Timepoint(s): Baseline, 6, 12, 18 weeks

Overall study start date
29/09/2014

Completion date
23/10/2018

Eligibility

Key inclusion criteria
1. Adult patients (aged 18 years or over) attending St James University Hospital diagnosed with early breast or colorectal cancer requiring adjuvant systemic treatment, or gynaecological cancer requiring chemotherapy (recruitment may be extended in the main trial to include testicular cancer patients receiving systemic therapy)
2. Prescribed at least three months of planned chemotherapy cycles at the time of study consent
3. Able and willing to give informed consent
4. Able to read and understand English
5. Access to the internet at home

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 568; UK Sample Size: 568

Total final enrolment
508

Key exclusion criteria
Patients who are:
1. Taking part in other clinical trials involving the completion of extensive patient reported outcome or quality of life measures
2. Exhibiting overt psychopathology/cognitive dysfunction

Date of first enrolment
26/01/2015

Date of final enrolment
11/06/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Beckett Street
Leeds
United Kingdom
LS9 7TF

Sponsor information

Organisation
University of Leeds (UK)

Sponsor details
Faculty of Medicine and Health
Academic Unit of Musculoskeletal and Rehabilitation Medicine
36 Clarendon Road
Leeds
England
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Sponsor type
University/education

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Government

Funder Name
NIHR Programme Grants for Applied Research; Grant Codes: RPPG061120008

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?
Protocol article	protocol	08/05/2017		Yes	No
Results article	results	01/03/2021	11/01/2021	Yes	No
HRA research summary			28/06/2023	No	No