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

Recruitment status No longer recruiting	[X] Prospectively registered		
	[X] Protocol		
Overall study status Completed	Statistical analysis plan		
	[X] Results		
Condition category	[] Individual participant data		
	No longer recruiting Overall study status Completed		

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

Contact name

Dr Kate Absolom

Contact details

Beckett Street Leeds United Kingdom LS9 7TF

LJJ

k.l.absolom@leeds.ac.uk

Additional identifiers

Protocol serial number 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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s))

- 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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

ΔII

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

United Kingdom

England

Study participating centre Beckett Street Leeds United Kingdom LS9 7TF

Sponsor information

Organisation

University of Leeds (UK)

ROR

https://ror.org/024mrxd33

Funder(s)

Funder type

Government

Funder Name

NIHR Programme Grants for Applied Research; Grant Codes: RPPG061120008

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type

Details results

Date created Date added Peer reviewed? Patient-facing?

Results article	protocol	01/03/2021	11/01/2021	Yes	No
<u>Protocol article</u>		08/05/2017		Yes	No
HRA research summary	Participant information sheet		28/06/2023		No
Participant information sheet		11/11/2025	11/11/2025	No	Yes