

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

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|--|---|--|
| Submission date 11/09/2014 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol |
| Registration date 11/09/2014 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 11/01/2021 | Condition category Cancer | <input type="checkbox"/> 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

United Kingdom

LS2 9NZ

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 |