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Delivery of cancer systemic therapy in patient's home, outreach surgery and hospital day unit

Submission date	Recruitment status	[_] Prospectively registered
18/06/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
18/06/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
26/10/2022	Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/trial-looking-at-comparing-the-delivery-of-treatment-for-cancer-in-the-community-and-hospital-OUTREACH

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
5700

Study information

Scientific Title
A randomised trial comparing delivery of cancer systemic therapy in three different settings: patient's home, outreach surgery and hospital day unit

Acronym
OUTREACH

Study objectives
This is a randomised, prospective controlled trial to determine the true benefits and costs of delivering systemic therapy to cancer patients in two different community settings - at home or in an outreach surgery - compared with standard delivery of treatment in hospital facilities, in terms of patient-perceived benefits, cost-effectiveness and patient safety.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cambridgeshire 2 Research Ethics Committee approved in August 2008 (ref: 08/H0308/130)

Study design
Multicentre randomised interventional treatment trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: National Cancer Research Network; Subtopic: All Cancers/Misc Sites; Disease: All

Interventions
The trial runs for 4 months with no patient follow up after that period. Three arms of the trial are treatment at home, treatment at a designated outreach surgery and at hospital day unit - this can be described as the control arm of the trial.

Study entry: single randomisation only

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Patient perceived benefits, measured by questionnaire at 0 weeks, 4 weeks, 8 weeks and 12 weeks with an optional 24 weeks visit.

Key secondary outcome(s))
1. Additional patient perceived benefits, measured by questionnaire at 0 weeks, 4 weeks, 8 weeks and 12 weeks with an optional 24 weeks visit
2. Impact on costs, measured by questionnaire at 0 weeks and 12 weeks

Completion date

31/03/2011

Eligibility

Key inclusion criteria
1. Any cancer patient being treated at either Cambridge University Hospital (CUH) or West Suffolk Hospital (WSH)
2. Prepared to be considered for treatment at home or at one of the three defined outreach surgeries as alternatives to standard hospital treatment
3. Life expectancy greater than 6 months
4. Either commencing a course of treatment planned to last a minimum of 3 months, or having already commenced a course of treatment which is planned to continue for a minimum of 3 further months
5. Course of treatment may be aimed at cure, palliation or supportive care
6. Has hot and cold running water
7. Has an indoor toilet
8. Has a working telephone
9. Is not dependant on hospital transport
10. Able to give written informed consent
11. Aged greater than 18 years
12. No other acute or chronic medical or psychiatric conditions which might have a significant influence on choice of the appropriate location of the patient to receive treatment
13. Easter Cooperative Oncology Group (ECOG) performance status less than 2; if ECOG PS 2, there must be a second individual living in the home who functions as a carer
14. Either sex, lower age limit of 18 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
97

Key exclusion criteria
1. Any patient receiving an unlicensed cancer drug treatment as part of a clinical trial, where the drug is defined as an investigational medical product (IMP), unless the trial itself has received ethics and research and development approval to be conducted in designated community settings used in the Outreach Trial
2. Patients with language barriers or communication difficulties whose safety might potentially

be compromised by entry into this trial (in the opinion of the Investigator)
3. Any patient, where, in the opinion of the investigator, entry into this trial would give cause for concern regarding patient safety

Date of first enrolment
01/11/2008

Date of final enrolment
31/03/2011

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Addenbrookes Hospital
Cambridge
United Kingdom
CB2 0QQ

Sponsor information

Organisation
Cambridge University Hospitals NHS Foundation Trust (UK)

ROR
https://ror.org/04v54gj93

Funder(s)

Funder type
Government

Funder Name
Research for Patient Benefit Programme (ref: PB-PG-0107-12101)

Alternative Name(s)
NIHR Research for Patient Benefit Programme, Research for Patient Benefit (RfPB), The NIHR Research for Patient Benefit (RfPB), RfPB

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	17/09/2013		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Plain English results			26/10/2022	No	Yes