

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

<b>Submission date</b> 18/06/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 18/06/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 26/10/2022	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## 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

### Contact name

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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**

## 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. Eastern 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?
<a href="#">Results article</a>	results	17/09/2013		Yes	No
<a href="#">Plain English results</a>			26/10/2022	No	Yes