

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

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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 below to request a patient information sheet

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 measure

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

Secondary outcome measures

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

Overall study start date

01/11/2008

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. 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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned sample size: 390; UK sample size: 390

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**

England

United Kingdom

Study participating centre

Addenbrookes Hospital

Cambridge

United Kingdom

CB2 0QQ

Sponsor information**Organisation**

Cambridge University Hospitals NHS Foundation Trust (UK)

Sponsor details

Addenbrookes Hospital
Hills Road
Cambridge
England
United Kingdom
CB2 0QQ

Sponsor type

Hospital/treatment centre

Website

http://www.cuh.org.uk/addenbrookes/addenbrookes_index.html

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, RfPB

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications**Publication and dissemination plan**

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan**

Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

Study outputs

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