

Port-a-cath and Hickman line devices for chemotherapy delivery

Submission date 25/01/2013	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 06/03/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 01/03/2019	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

<http://www.cancerresearchuk.org/cancer-help/trials/a-study-comparing-two-different-types-central-lines-people-due-start-course-chemotherapy>

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

Protocol/Serial No: MI93

Study information

Scientific Title

Port-a-cath and Hickman line devices for chemotherapy delivery: A randomised phase II study and pre-trial economic model development to inform the design of a subsequent randomised phase III controlled trial

Study objectives

The study hypothesis is that Ports are cost effective for the delivery of chemotherapy and that it is not appropriate to deny these devices to patients on grounds of purchasing costs alone. Although Ports are a little more difficult to insert and more expensive than Hickman lines, they carry potential advantages such as reduced infection and re-intervention rates, reduced maintenance and superior patient acceptability.

Ethics approval required

Old ethics approval format

Ethics approval(s)

West of Scotland REC 1, 05/04/2011, ref: 11/AL/0083

Study design

Multi-centre open randomised study

Primary study design

Interventional

Study type(s)

Screening

Health condition(s) or problem(s) studied

Cancer, Chemotherapy, device study

Interventions

Patients will be randomised in a 3:1 ratio to receive either a Hickman line (n=75) or a Port-a-cath (n=25).

Patients participating in the study will be asked to complete quality of life questionnaires (EQ-5D and device-specific) at baseline and subsequently monthly (sent out to the patients at home) during the insertion period; a further questionnaire will be completed at the time of planned line removal.

Patients will be seen as per standard of care for their treatment. Complication forms will be completed on a monthly basis by CTU Glasgow staff.

Intervention Type

Device

Phase

Phase II

Primary outcome(s)

Cost effectiveness of Ports

Key secondary outcome(s)

Complication data including line infection (with and without antibiotics), tract infection, (with /without antibiotics), occlusion, migration, loss of line, central vein thrombosis, exit site haematoma, and skin breakdown will be recorded by clinical staff, on complication forms in case notes, as events occur and data collected by the clinical trial coordinator. Reinterventions including line replacement, thrombolysis, stripping and manipulations will be recorded by clinical staff, on complication forms in case notes, as events occur and data collected by the clinical trial coordinator.

Completion date

01/07/2013

Eligibility

Key inclusion criteria

1. Oncology patients with solid tumours who are scheduled for access line insertion
2. Patients must be willing and clinically able to receive either a Hickman line or a Port-a-cath
3. Patient must provide informed consent
4. Age \geq 18 years, male and female
5. Able to comply with study protocol

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Any evidence of any medical or psychiatric disorders that would be a contra indication to study participation
2. Life expectancy < 3 months

Date of first enrolment

09/08/2011

Date of final enrolment

01/07/2013

Locations

Countries of recruitment

United Kingdom

Scotland

Study participating centre
Gartnavel General Hospital
Dept of Radiology
1053 Great Western Road
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G12 0DY

Study participating centre
Inverclyde Royal Hospital
Larkfield Road
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PA16 0XN

Sponsor information

Organisation
NHS Greater Glasgow and Clyde (UK)

ROR
<https://ror.org/05kdz4d87>

Funder(s)

Funder type
Government

Funder Name
Chief Scientist Office (UK) - Scottish Government (CZG/2/512)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results:	26/04/2016		Yes	No