ISRCTN79422566 https://doi.org/10.1186/ISRCTN79422566

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

Submission date	Recruitment status	[_] Prospectively registered
25/01/2013	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
06/03/2013	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
01/03/2019	Cancer	

Plain English Summary
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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 hypothesis
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
Not available in web format, please contact Judith Dixon [judith.dixon@glasgow.ac.uk] to request a patient information sheet

Condition
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 measure
Cost effectiveness of Ports

Secondary outcome measures
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.

Overall study start date
01/08/2011

Overall study end date
01/07/2013

Eligibility

Participant 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 ≥18 years, male and female
5. Able to comply with study protocol

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

100

Participant 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

Recruitment start date
09/08/2011

Recruitment end date
01/07/2013

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Gartnavel General Hospital
Dept of Radiology
1053 Great Western Road
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Study participating centre
Inverclyde Royal Hospital
Larkfield Road
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PA16 0XN

Sponsor information

Organisation
NHS Greater Glasgow and Clyde (UK)

Sponsor details
c/o Dr Nathaniel Brittain
Academic Research Co-ordinator

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Western Infirmary
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Sponsor type
Hospital/treatment centre

Website
http://www.nhsggc.org.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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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