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CAVA - Cancer And Venous Access

Submission date 21/03/2013	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 26/03/2013	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 22/07/2022	**Condition category** Cancer	[_] Individual participant data

Plain English Summary
http://www.cancerresearchuk.org/cancer-help/trials/a-trial-looking-central-lines-for-long-term-chemotherapy-cava

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CAVA 2013

Study information

Scientific Title
Cancer And Venous Access (CAVA) A randomised controlled trial with associated qualitative research of venous access devices for the delivery of long-term chemotherapy

Acronym
CAVA

Study hypothesis
To determine which venous access device - subcutaneously tunnelled central catheters (Hickman type device), peripherally inserted central catheters (PICC) or implantable chest wall ports (Port) - offers the best outcome from safety, clinical effectiveness and cost effectiveness perspectives.

More details can be found at http://www.hta.ac.uk/2985

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval has been sought from the West of Scotland REC 1. Reference Number: 13/WS /0056. Provisional approval for the CAVA trial was received on 11/03/2013.

Study design
Randomised controlled trial incorporating pre and post trial qualitative research

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Condition
Venous Access in Cancer Patients

Interventions
All patients will receive either a Port, PICC or Hickman Type device. There are four possible randomisation options for each patient. The site or patient will chose which randomisation option to be part of and then the patient will be randomised between the possible devices in that option. The options are:
Hickman type device versus PICC
Hickman type device versus chest wall port

PICC versus chest wall port
Hickman type device versus PICC versus chest wall port

Intervention Type
Device

Phase
Not Applicable

Primary outcome measure
The primary outcome for the randomised trial is complication rate, a composite of infection (suspected or confirmed) and/or mechanical failure. This will be analysed using logistic regression including terms for treatment group and randomisation stratification factors.

Secondary outcome measures
An analysis will also be conducted based on complication event rate data 13. This analysis will estimate the effect of the access devices on the individual component complications (infections and mechanical failure) and will allow an assessment of the similarity of these effects via a likelihood ratio test. The incidence of venous thrombosis will be compared using logistic regression and also as an event rate. The frequency of the various complications will be assessed. The total duration of treatment interruptions will be summarised and compared using a Mann Whitney U-test.

Scores for the five dimensions of the EQ-5D (mobility, self-care, usual activities, pain/discomfort and anxiety/depression) and the visual analogue score for health will be summarised and the EQ-5D curves will be compared between treatment groups using an area under curve (AUC) approach standardised for the period on study and using the baseline value as a covariate.

Scores for the 5 functional scales (physical, role, emotional, cognitive, social) and 9 symptom scales (fatigue, nausea and vomiting, pain, dyspnoea, insomnia, appetite loss, constipation, diarrhoea, financial difficulties) of the EORTC QLQ-C30 will be calculated according to standard EORTC conventions, as will global health status score. These scores will be summarised and analysed as EQ-5D.

The results from the device-specific questionnaire will be summarised only.

Overall study start date
01/06/2013

Overall study end date
30/09/2019

Eligibility

Participant inclusion criteria
1. Aged ≥ 18 years
2. Receiving or to receive chemotherapy
3.Duration of chemotherapy ≥ 12 weeks
4. Clinical team uncertain as to which device is optimal for this indication
5. Solid or haematological malignancy
6. Suitable upper extremity vein for all the access devices to which the patient may be

randomised
7. Able to provide written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
2000

Total final enrolment
1061

Participant exclusion criteria
1. Life or treatment expectancy <3 months
2.Previous venous access device removed due to complication within last three months
3. Requirement for high volume (apheresis) line
4. Need for catheter to be placed in a non upper extremity vein
5. Patient previously randomised into the CAVA tria

Recruitment start date
01/06/2013

Recruitment end date
28/02/2019

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Gartnavel General Hospital
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Sponsor information

Organisation
NHS Greater Glasgow and Clyde (UK)

Sponsor details
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Sponsor type
Government

ROR
https://ror.org/05kdz4d87

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment (HTA) programme (project reference 11/67/01).

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date
01/02/2020

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	patient acceptability qualitative results	09/07/2019	04/08/2020	Yes	No
Results article	results	20/07/2021	27/07/2021	Yes	No
Results article		01/07/2021	29/07/2021	Yes	No
Plain English results	CRUK plain English summary and results	22/07/2022	22/07/2022	No	Yes
HRA research summary			28/06/2023	No	No