

CAVA - Cancer And Venous Access

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

Plain English summary of protocol

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

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

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 objectives

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.

Primary study design

Interventional

Study design

Randomised controlled trial incorporating pre and post trial qualitative research

Study type(s)

Treatment

Health condition(s) or problem(s) studied

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(s)

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.

Key secondary outcome(s)

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.

Completion date

30/09/2019

Eligibility**Key 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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Total final enrolment

1061

Key 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 trial

Date of first enrolment

01/06/2013

Date of final enrolment

28/02/2019

Locations

Countries of recruitment

United Kingdom

Scotland

Study participating centre

Gartnavel General Hospital

Glasgow

United Kingdom

G12 0YN

Sponsor information

Organisation

NHS Greater Glasgow and Clyde (UK)

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

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
HRA research summary			28/06/2023	No	No
Plain English results	CRUK plain English summary and results	22/07/2022	22/07/2022	No	Yes