

# CAVA - Cancer And Venous Access

<b>Submission date</b> 21/03/2013	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 26/03/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 22/07/2022	<b>Condition category</b> Cancer	<input type="checkbox"/> 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

Prof Jon Moss

### Contact details

Professor Jon Moss  
Interventional Radiology Unit  
Gartnavel General Hospital  
1053 Great Western Road  
Glasgow  
United Kingdom  
G12 0YN  
-  
jon.moss@ggc.scot.nhs.uk

## 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 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.

## Study design

Randomised controlled trial incorporating pre and post trial qualitative research

## Primary study design

Intentional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

## 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 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

## **Completion date**

30/09/2019

## **Eligibility**

### **Key inclusion criteria**

1. Aged  $\geq 18$  years
2. Receiving or to receive chemotherapy
3. Duration of chemotherapy  $\geq 12$  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

**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**

Scotland

United Kingdom

**Study participating centre**

**Gartnavel General Hospital**

Glasgow

United Kingdom

G12 0YN

# Sponsor information

## Organisation

NHS Greater Glasgow and Clyde (UK)

## Sponsor details

Dr Nathaniel Brittain  
Academic Research Co-ordinator  
NHS Greater Glasgow and Clyde  
Research and Development Central Office  
The Tennent Institute, 1st Floor  
Western Infirmary General  
38 Church Street  
Glasgow  
United Kingdom  
G11 6NT

-  
Nathaniel.Brittain@ggc.scot.nhs.uk

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