

# Intraoperative cell salvage vs transfusion in ovarian cancer

<b>Submission date</b> 07/11/2016	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 11/11/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 22/05/2023	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

<https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-comparing-intraoperative-cell-salvage-and-blood-transfusions-for-women-having-surgery-for-ovarian-cancer>

## Contact information

### Type(s)

Public

### Contact name

Ms Jane Vickery

### Contact details

Peninsula Clinical Trials Unit  
N16, ITTC Building 1  
Plymouth Science Park  
Plymouth  
United Kingdom  
PL6 8BX  
+44 (0)1752 315250  
jane.vickery@plymouth.ac.uk

## Additional identifiers

### Protocol serial number

31586

## Study information

### Scientific Title

A randomised controlled feasibility Trial of Intraoperative Cell salvage vs donor blood Transfusion in Ovarian Cancer surgery (TICTOC)

## **Acronym**

TICTOC

## **Study objectives**

The aim of this study is to test the processes for a larger definitive trial, ascertain its feasibility and provide the necessary information to plan a full trial, assessing the clinical and cost effectiveness of intra-operative cells salvage for women undergoing surgery for ovarian cancer, compared with the usual practice of transfusing donor blood.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

South West - Exeter Research Ethics Committee, 14/10/2016, ref: 16/SW/0256

## **Study design**

Randomised; Interventional; Design type: Treatment, Process of Care, Management of Care, Surgery

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Specialty: Cancer, Primary sub-specialty: Gynae; UKCRC code/ Disease: Cancer/ Malignant neoplasms of female genital organs

## **Interventions**

Sixty participants will be randomised in a 1:1 ratio to intraoperative cell salvage (ICS, re-infusion of their own blood) or donor blood transfusion during surgery. Participants and outcome assessors will be blinded to the intervention.

For all participants the standard operative procedure for ovarian cancer (cytoreductive surgery) will be performed. If intraoperative transfusion is required, the participant will receive either ICS or donor transfusion according to treatment allocation. Some participants may not require any intraoperative transfusion and some (either arm of the trial) may require donor blood transfusion post-operatively.

Intra-operative cell salvage arm: The cell salvage system to be used in this study is the Haemonetics Cell Saver® 5+ autologous blood recovery system. All sites will follow a common ICS protocol. Collected blood will be processed using a 125ml bowl before being re-infused via a leucodepletion filter. All full bowls of salvaged blood will be reinfused back to the participant during, or at the end of, the operative procedure. ICS blood will be returned even if only small

quantities are lost. Participants allocated to the ICS arm who also need donor transfusion for clinical reasons can be given donor blood at any time, during or after surgery, for the duration of their hospital stay.

Donor transfusion arm: Participants allocated to donor transfusion will be considered for intraoperative transfusion in accordance with clinical judgement, guided by local hospital policy. Donor blood transfusion may also be given post-operatively in accordance with usual clinical care. Donor blood will only be given (in standard volumes) when deemed necessary (e.g. after substantial blood loss and/or drop in haemoglobin).

Trial treatment is confined to the intra-operative period only.

All participants will be followed up at 30 days post-operatively, by telephone, for adverse events reporting and 6 weeks and 3 months post-operatively by post. In addition, participants recruited in the early part of the study will be followed up by post at subsequent three month intervals (at 6 and 9 months) as time allows.

## **Intervention Type**

Other

## **Primary outcome(s)**

Feasibility outcomes:

1. Recruitment rate is recorded as the number of eligible participants who consent to participate in the study by 12 months
2. Feasibility of randomisation immediately pre-operatively is recorded by the time interval between randomisation and beginning of surgery
3. Attrition rate is recorded as the number of participants who consent to participate that remain in the study until the end of follow up at three months
4. Completeness of proposed outcome measures will be recorded as the number of complete specific data fields within CRFs and patient questionnaire booklets received at end of follow up at three months, out of the expected total number of CRFs and booklets
5. Success of blinding of allocation for participants and outcome assessor will be recorded by the number of participants and assessors who are inadvertently made aware of their treatment allocation during the trial period
6. Success of data collection tools and methods to collect resource use data will be recorded as the proportion of completed resource use data fields available at end of follow-up
7. Acceptability of the intervention to participants will be assessed by qualitative interviews
8. Acceptability of study participation to participants will be assessed by qualitative interviews

## **Key secondary outcome(s)**

No secondary outcome measures

## **Completion date**

30/06/2018

## **Eligibility**

### **Key inclusion criteria**

1. 18 years old or over
2. Suspected or confirmed ovarian cancer (newly diagnosed) requiring cytoreductive surgery, whether primary or interval (following chemotherapy)

3. CT scan evidence (with or without clinical evidence) compatible with FIGO stage III/IV ovarian cancer/ primary peritoneal cancer at presentation\*
4. ECOG Performance Status 0-1
5. Willing to participate and able to give written informed consent

\*CT features of pelvic mass (or features suggestive of primary peritoneal cancer) and extrapelvic involvement including ascites, omental disease, peritoneal thickening, bowel surface and/or mesentery involvement, enlarged pelvic and para-aortic lymph nodes, evidence of disease on diaphragm

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

Female

**Total final enrolment**

57

**Key exclusion criteria**

1. Diagnosis of concurrent malignancy
2. Pregnant
3. Donor transfusion during the week prior to surgery
4. Haemoglobinopathies (e.g. sickle cell, thalassaemia)
5. Unwilling to accept donor blood (e.g. on religious grounds)

**Date of first enrolment**

17/01/2017

**Date of final enrolment**

28/02/2018

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Royal Cornwall Hospital**

2 Penventinnie Lane  
Treliske  
Truro  
United Kingdom  
TR1 3LJ

**Study participating centre****Derriford Hospital**

Derriford Road  
Plymouth  
United Kingdom  
PL6 8DH

**Study participating centre****Queen Elizabeth Hospital**

Queen Elizabeth Avenue  
Sheriff Hill  
Gateshead  
United Kingdom  
NE9 6SX

## Sponsor information

**Organisation**

Royal Cornwall Hospitals NHS Trust

**ROR**

<https://ror.org/026xdc93>

## Funder(s)

**Funder type**

Government

**Funder Name**

National Institute for Health Research

**Alternative Name(s)**

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

### Funding Body Type

Government organisation

### Funding Body Subtype

National government

### Location

United Kingdom

## Results and Publications

### Individual participant data (IPD) sharing plan

The current data sharing plans for the current study are unknown and will be made available at a later date.

### IPD sharing plan summary

Data sharing statement to be made available at a later date

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	01/11/2018	01/11/2019	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Plain English results</a>			22/05/2023	No	Yes