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Intraoperative cell salvage vs transfusion in ovarian cancer

Submission date 07/11/2016	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 11/11/2016	**Overall study status** Completed	
Last Edited 22/05/2023	**Condition category** Cancer	

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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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 measure
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

Secondary outcome measures

No secondary outcome measures

Overall study start date
01/07/2016

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

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
Planned Sample Size: 60; UK Sample Size: 60

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
England

United Kingdom

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

Sponsor details

Research, Development & Innovation Manager
Knowledge Spa
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TR1 3LJ

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/026xdcm93

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

Publication and dissemination plan
The study team will prepare a plain English summary of the study results which will be made available to study participants as soon as possible after the end of the study (June 2018). The final results of the study will be disseminated via presentations at appropriate scientific meetings and conferences and publication in appropriate peer-reviewed journals. Indicative publication date end 2018.

Intention to publish date

31/12/2018

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?
Protocol article	protocol	01/11/2018	01/11/2019	Yes	No
Plain English results			22/05/2023	No	Yes
HRA research summary			28/06/2023	No	No