ISRCTN12469865 https://doi.org/10.1186/ISRCTN12469865

Patient perspectives on peritoneal metastasis treatments

Submission date 06/11/2017	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 05/01/2018	**Overall study status** Stopped	
Last Edited 15/11/2018	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
The aim of this study is to assess the perception of patients towards three different treatment options for the palliative treatment of cancer which has spread within the abdominal cavity (disseminated peritoneal adenocarcinoma). Adjuvant chemotherapy involves medication (chemotherapy) being given in addition to surgery in order to reduce the risk of the cancer coming back. Pressurised intra peritoneal aerosol chemotherapy (PIPAC) involves chemotherapy being sprayed in the abdomen, while hyperthermic intraperitoneal chemotherapy (HIPEC) involves heated chemotherapy treatment delivered directly to the abdomen. PIPAC is currently only able to be offered to patients in a limited feasibility capacity.

Who can participate?
Patients aged over 18 who are being treated with adjuvant chemotherapy, HIPEC or PIPAC for disseminated peritoneal adenocarcinoma

What does the study involve?
Participants are interviewed about their perspective and attitudes to the treatment option and their quality of life is assessed before treatment starts and for up to 3 months during treatment. Demographic data is collected from those patients who are offered PIPAC to determine if there are any factors associated with take up of the new treatment.

What are the possible benefits and risks of participating?
In order to allow future research and expansion of the treatment options available for patients, it is important to understand patients' concerns, questions and expectations before and how they may change following treatment. This study will enable the development of patient information material for future studies and also to identify which patient groups (if any) are more or less likely to opt for new/innovative treatments.

Where is the study run from?
1. Cwm Taf University Health Board (UK)
2. Cardiff and Vale University Health Board (UK)

When is the study starting and how long is it expected to run for?
September 2017 to November 2018

Who is funding the study?
Tenovus (UK)

Who is the main contact?
Julie Cornish

Contact information

Type(s)
Scientific

Contact name
Mrs Julie Cornish

Contact details
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Cardiff
United Kingdom
CF14 4XW

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1.0

Study information

Scientific Title
Patient Perspectives on Peritoneal Metastasis Treatments

Acronym
PerMeT

Study objectives
The trialists will approach all patients found to have intraperitoneal adenocarcinoma who are being considered for one of the three treatments (palliative chemotherapy, ePIPAC or HIPEC). The aim of this study is to assess patient attitudes and perspectives on new innovations for cancer surgery before and after treatment. In addition information on key concerns of patients around each treatment option will be captured.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Wales REC, 14/09/2017, ref: 17/WA/0247

Study design
Qualitative study

Primary study design
Observational

Secondary study design
Qualitative study

Study setting(s)
Hospital

Study type(s)
Quality of life

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

Health condition(s) or problem(s) studied
Adenocarcinoma with peritoneal metastases

Interventions
4-8 patients are recruited from each of the three treatment groups:
1. Adjuvant chemotherapy
2. HIPEC (hyperthermic intraperitoneal chemotherapy)
3. PIPAC

Over a 12-month period face to face interviews are performed and quality of life data are collected before treatment commences and for up to 3 months during treatment. Baseline demographic data of those patients being offered PIPAC are collected to determine if there are any associated factors with take up of the new treatment.

Intervention Type
Other

Primary outcome measure
Patient's perspective and attitudes to the treatment option, assessed using qualitative interviews and focus groups at baseline and 3 months

Secondary outcome measures
1. Quality of life, measured using EQ5D
2. Personality profile of the patient and attitude of risk, assessed using Ten Item Personality inventory
3. Side effects experienced, assessed using patient diary and qualitative interviews
Measured at baseline and 3 months, with the patient diary also being assessed at 6 weeks

Overall study start date
01/09/2017

Completion date
01/11/2018

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
1. Patients with disseminated peritoneal adenocarcinoma (of ovarian or colorectal origin)
2. Patients who are due to undergo treatment with; palliative chemotherapy OR HIPEC (Hyperthermic intraperitoneal chemotherapy) OR ePIPAC (electrostatic pressurised intra peritoneal aerosol chemotherapy)
3. Patients >18 years of age
4. Patients who are able to give informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
8-12 per group (max 24)

Key exclusion criteria
Unable to give informed consent

Date of first enrolment
01/10/2017

Date of final enrolment
01/10/2018

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Cwm Taf University Health Board
Royal Glamorgan Hospital
Llantrisant
United Kingdom
CF72 8XR

Study participating centre
Cardiff and Vale University Health Board
Cardiff
United Kingdom
CF14 4XW

Sponsor information

Organisation
Cwm Taf University Health Board

Sponsor details
Royal Glamorgan Hospital
Llantrisant
Wales
United Kingdom
CF72 8XR

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00rh52j13

Funder(s)

Funder type
Charity

Funder Name
Tenovus

Alternative Name(s)

Tenovus Cancer Care

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Publication and dissemination plan as of 15/11/2018:
A final report will be published through Tenovus, the charity that funded the study.

Previous publication and dissemination plan:
Planned submission of the protocol for publication in the next 3 months. Planned publication of the results in a high impact peer reviewed journal around one year after the end of the trial.

Intention to publish date
01/11/2019

Individual participant data (IPD) sharing plan
The 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?
HRA research summary			28/06/2023	No	No