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Short term Water-only Fasting prior to chemotherapy Trial (SWiFT)

Submission date
14/09/2018

Recruitment status
Suspended

Registration date
23/10/2018

Overall study status
Completed

Last Edited
27/04/2020

Condition category
Cancer

[X] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English Summary

Background and study aims
We would like to find out whether it is possible for people to follow a short-term fast before their chemotherapy. Fasting involves avoiding all food for a set amount of time. Some research suggests that fasting might help to protect our cells during chemotherapy, by switching them from a state of growth and development to a state of maintenance and repair. However, we don't know if fasting is of benefit. Ultimately, we would like to find out whether fasting before chemotherapy can help to reduce its side effects. In order to answer this question, we first need to find out whether it is possible for people to fast before their chemotherapy. This has been tested in some previous studies but not in people receiving chemotherapy for colorectal cancer. So, we are inviting 30 people to take part in a trial that will compare a 36-hour fast to usual diet before chemotherapy.

Who can participate?
Adults with stage 2 or 3 colorectal cancer who are due to receive capecitabine oxaliplatin (CAPOX) chemotherapy.

What does the study involve?
Participants will be randomly allocated to either the intervention group or the control group. The intervention group will spend 36 hours prior to their chemotherapy fasting and drinking water-only. Each chemotherapy cycle will be 21 days long and participants in this group will fast before each of their first 3 cycles of chemotherapy.
The control group will receive the usual advice prior to their first cycle of chemotherapy, including written or verbal information on their diet and the effects of chemotherapy on appetite.

What are the possible benefits and risks of participating?
We do not know whether there are any benefits to either fasting or consuming a normal diet before CAPOX chemotherapy. Although participants may not receive any extra benefit from taking part in this trial, research like this helps to continually improve the treatments and care provided to all patients now and in the future. There are only minimal risks involved in this

research. Potential side effects of short-term fasting are headaches, dizziness, tiredness, hunger, weight loss and low blood pressure. However, these effects are normally mild and will resolve themselves once fasting has ended.

Where is the study run from?:
1. NIHR Biomedical Research Centre at University Hospitals Bristol NHS Foundation Trust (UK)
2. University of Bristol (UK)

When is the study starting and how long is it expected to run for?
October 2017 to April 2021

Who is funding the study?
1. NIHR Biomedical Research Centre at University Hospitals Bristol NHS Foundation Trust (UK)
2. University of Bristol (UK)

Who is the main contact?
Ellie Shingler
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
3007

Study information

Scientific Title

Short term Water-only Fasting prior to chemotherapy Trial: a randomised controlled feasibility trial of fasting prior to CAPOX chemotherapy for stage 2/3 colorectal cancer

Acronym
SWiFT

Study hypothesis
Short-term fasting may offer protection for healthy cells from the side effects of chemotherapy. However, it is not known whether it is possible to recruit people with colorectal cancer to a trial of short-term fasting, or whether participants would be able to adhere to the intervention. Therefore, we aim to test the feasibility of a pre-chemotherapy, 36-hour, water only fast in people receiving CAPOX chemotherapy for stage 2/3 colorectal cancer.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 08/01/2019, South West - Frenchay Research Ethics Committee (Level 3, Block B Whitefriars Lewins Mead, Bristol, BS1 2NT, UK; Tel: +44 (0)207 104 8041; Email: nrescommittee.southwest-frenchay@nhs.net), ref: 18/SW/0254

Study design
Interventional two-armed randomised controlled feasibility trial

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 contact details to request a participant information sheet

Condition
Colorectal cancer

Interventions
Participants will be randomly allocated, in a 1:1 ratio, to either a 36-hour fast (intervention arm) or standard dietary advice (control arm). Randomisation will be completed in a 1:1 ratio using random permuted blocks using a secure online randomisation system.
In the intervention arm, participants will undertake a 36-hour water only fast, immediately prior to chemotherapy administration. Each chemotherapy cycle lasts 21 days, and they will fast before each of their first 3 cycles of chemotherapy (a total of 3 short-term fasts). They will be followed up until day 7 of cycle 3.

In the control arm, participants will receive standard dietary guidance/advice as per local standard practice prior to their first cycle of chemotherapy. This may include verbal or written information on diet and effects of chemotherapy on appetite. They will be followed up until day 7 of cycle 3.

Intervention Type
Behavioural

Primary outcome measure
Feasibility of the trial:
1. Adherence to intervention, assessed by analysis of self-reported hour food logs, completed by participants during the 36-hour fast. Participants will be considered to have adhered to the fast if they consume less than 14% of their Basal Metabolic Rate (BMR) requirements (kcal/day calculated using the Oxford equations for BMR), in the 36 hours prior to chemotherapy administration. The percentage of adherent participants will be reported for each cycle. Reasons for non-adherence will also be recorded.
2. Recruitment rates, calculated as the percentage of eligible patients recruited each month, as recorded in the recruitment logs at each site.
3. Retention rates, calculated as the number of participants who completed data collection for each fasting cycle divided by the number of participants randomised.
4. Acceptability and tolerability of the intervention, qualitatively assessed through in depth semi-structured interviews with a subset of the trial participants when they have completed the trial
5. Data completion rates, assessed by calculating data completeness for all measures at each cycle

Secondary outcome measures
1. Side effects of chemotherapy, assessed on day 1 of each cycle prior to administration, and then as a follow-up on day 3 and day 7 using:
1.1. Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE™)
1.2. Full Blood Count (FBC)
1.3. Blood chemistry analysis
Data will also be recorded on whether participants completed their first 3 cycles of chemotherapy and reasons for dose reductions/delays/early termination.
2. Quality of Life, assessed using the EQ-5D-5L health-related quality of life instrument at the baseline and days 1, 3 and 7 of each cycle
3. Haematologic toxicities, assessed using routine FBC data collected prior to each round of chemotherapy and classified according to CTCAE criteria
4. Markers of cellular metabolism - baseline samples will be collected prior to fasting and follow-up samples will be collected prior to chemotherapy administration at cycles 1 and 3. Measures will include:
4.1. Glucose (measured from blood samples)
4.2. Insulin (measured from blood samples)
4.3. IGF-I (measured from serum samples)
4.4. IGF-II (measured from serum samples)
4.5. IGFBP-2 (measured from serum samples)
4.6. IGFBP-3 (measured from serum samples)
5. Markers of inflammation (C-reactive protein (CRP)) measured from blood samples at the baseline (pre-fast) and prior to chemotherapy administration at cycles 1 and 3
6. Appetite, assessed using visual analogue scales (VAS) at the baseline and days 1, 3 and 7 of each cycle

7. Sarcopenia, assessed using the following at the baseline and at cycle 3, along with at staging and follow-up CT scans:
7.1. Computerised Tomography (CT)
7.2. Hand grip dynamometer

Overall study start date
02/10/2017

Overall study end date
30/04/2021

Eligibility

Participant inclusion criteria
1. Aged 18 years or older
2. Histologically confirmed stage 2/3 colorectal cancer which is being treated with adjuvant CAPOX chemotherapy
3. Performance status ≤2
4. Able to provide written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30

Participant exclusion criteria
1. Confirmed cachexia
2. Confirmed diabetes
3. Body mass index (BMI) ≤18.5 kg/m²
4. History of an eating disorder
5. Recent history of drug or alcohol abuse
6. Participating in another study that may affect the outcomes of this feasibility trial
7. Unable to speak/understand English

Recruitment start date
02/09/2019

Recruitment end date
31/12/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Hospitals Bristol NHS Foundation Trust
Upper Maudlin Street
Bristol
United Kingdom
BS2 8AE

Sponsor information

Organisation
University of Bristol

Sponsor details
Senate House
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Sponsor type
University/education

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Government

Funder Name
NIHR Biomedical Research Centre at University Hospitals Bristol NHS Foundation Trust and the University of Bristol

Results and Publications

Publication and dissemination plan

On completion of the trial, results will be submitted for publication to a peer reviewed journal. Findings will also be presented at relevant academic conferences and as part of Mrs Ellie Shingler's PhD Thesis. The NIHR Bristol Biomedical Research Centre is actively involved in public engagement activities, and trial results will be shared through appropriate public engagement opportunities. All trial participants and PPI group members will be asked to indicate whether they would like to be informed of the trial results, and a summary of the main findings will be distributed to those who express interest.

Intention to publish date

31/07/2021

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?
Protocol article	protocol	20/11/2019	16/12/2019	Yes	No
HRA research summary			28/06/2023	No	No