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

Submission date 14/09/2018	Recruitment status Suspended	[X] Prospectively registered[X] Protocol
Registration date	Overall study status	Statistical analysis plan
23/10/2018	Completed	☐ Results
Last Edited 27/04/2020	Condition category Cancer	☐ Individual participant data
		Record updated in last year

Plain English summary of protocol

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 ellie.shingler@bristol.ac.uk

Contact information

Type(s)

Public

Contact name

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Contact details

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Additional identifiers

Protocol serial number 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 objectives

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

Study type(s)

Treatment

Health condition(s) or problem(s) studied

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(s)

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 semistructured 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

Key secondary outcome(s))

- 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 followup 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

Completion date

30/04/2021

Eligibility

Key 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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key 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

Date of first enrolment

02/09/2019

Date of final enrolment

31/12/2020

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

University Hospitals Bristol NHS Foundation Trust

Upper Maudlin Street Bristol United Kingdom BS2 8AE

Sponsor information

Organisation

University of Bristol

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

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025 No	Yes