

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

<b>Submission date</b> 14/09/2018	<b>Recruitment status</b> Suspended	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 23/10/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 27/04/2020	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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**

Mrs Ellie Shingler

**Contact details**

Level 3, University Hospitals Bristol Education Centre

Upper Maudlin Street

Bristol

United Kingdom

BS2 8AE

+44 (0)117 34 21883

ellie.shingler@bristol.ac.uk

## 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 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

## **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

## **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 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

**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  $\leq 2$

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

**Key exclusion criteria**

1. Confirmed cachexia

2. Confirmed diabetes

3. Body mass index (BMI)  $\leq 18.5$  kg/m<sup>2</sup>

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

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

Tyndall Avenue

Bristol

England

United Kingdom

BS8 2PS

## 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?
<a href="#">Protocol article</a>	protocol	20/11/2019	16/12/2019	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No