

The microbiome of colorectal cancer patients at Tishreen University Hospital and Oncology Center: a focus on *Fusobacterium nucleatum*

Submission date 05/08/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 29/08/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 17/12/2024	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Colorectal cancer is a type of cancer that starts in the colon or rectum, often developing from growths called polyps.

The LAMP technique, or Loop-Mediated Isothermal Amplification, is a molecular biology method that allows scientists to rapidly and accurately amplify specific DNA sequences under constant temperature conditions. This technique has applications in various fields, including medical diagnostics, research, and disease detection. In the present study, our focus is on improving the LAMP technique by introducing a new method to analyze various samples. We plan to use colors and a substance called phenol red to make this possible, and we'll refer to it as Quantitative LAMP (QLAMP-phenol red).

The QLAMP-phenol red method aims to provide a precise way of measuring small things in biology, particularly beneficial for places with limited resources. It's designed to be straightforward, fast, accurate, reliable, and cost-effective. Additionally, the visual interpretation of color changes, observable with the naked eye, adds to its practicality.

In our research, we aim to identify a gene called *fadA* that could serve as a marker for detecting a specific bacteria called *Fusobacterium nucleatum*, associated with colorectal cancer. By designing specialized tools (akin to magnifying glasses) using the LAMP technique, we hope to enable early cancer detection in patients. Furthermore, we intend to enhance the LAMP technique's capabilities by integrating phenol red to ensure more precise measurements.

Who can participate?

Patients aged 18 - 80 years with colorectal cancer.

What does the study involve?

An administration of a Probiotic for 4 weeks. Stool sampling at baseline and 1, 2, 3, 4 weeks.

What are the possible benefits and risks of participating?
Each participant would be informed of the risks of the Probiotic by the supervising physician at the Tishreen Hospital-chemotherapy center.

Where is the study run from?
Tishreen University (Syria)

When is the study starting and how long is it expected to run for?
May 2019 to May 2023

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Abdulrahman Zuraik, abdulrahman.zuraik@tishreen.edu.sy

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
299

Study information

Scientific Title

Rapid detection of fadA in Fusobacterium nucleatum by the quantitative loop-mediated isothermal amplification colorimetric-phenol red method: a case control study

Study objectives

What is the role of Fusobacterium nucleatum in colorectal cancer?

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 14/06/2023, BioEthics committee - Tishreen university Human Research Ethics Board and Academic science Research Committee (Tishreen university, Latakia, -, Syria; +963-41-437480; inter-rel@tishreen.edu.sy), ref: 14062023

Study design

Interventional double blind randomized controlled trial

Primary study design

Interventional

Study type(s)

Diagnostic, Other, Prevention, Screening, Treatment

Health condition(s) or problem(s) studied

Colon cancer

Interventions

QLAMP-PR assays were tested on about 500 stool samples (250 CRC patients, 250 healthy controls) specifically for the FadA gene of F.nucleatum. Six primers were designed and synthesized with master mix reagents, and a phenol red indicator was applied to promote LAMP technique.

Samples were acquired before the administration of the probiotic and after it at 1, 2, 3, 4 weeks

Intervention Type

Genetic

Primary outcome(s)

A digital value of the F. nucleatum DNA copy number amount (or concentration with ng/ul) measured by LAMP protocol using a visible spectrophotometer at 420 nm, 500 nm and 560 nm at baseline and 1, 2, 3, 4 weeks

Key secondary outcome(s)

There are no secondary outcome measures

Completion date

16/05/2023

Eligibility

Key inclusion criteria

CRC patients:

1. Accepted in Tishreen Hospital-chemotherapy center
2. Individuals diagnosed with CRC between 11/2019 and 11/2020
3. Confirmation of the diagnosis through pathology reports.
4. Any CRC stage or grade
5. Has or hasn't had chemotherapy or colon surgery

Healthy controls:

1. Individuals without a history of colorectal cancer or colon polyps
2. Individuals without a history of any chronic bowel diseases (IBD, crown, IBS, ..) or any Gastrointestinal complaint (diarrhea, jaundice, hemorrhoids, bacterial enteritis, heartburn) for at least 3 weeks prior to the study sampling
3. Similar demographic characteristics to the patient group to minimize confounding factors.

Participant type(s)

Healthy volunteer, Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

80 years

Sex

All

Key exclusion criteria

CRC patients:

1. Individuals with a history of other cancers to maintain a homogeneous study population
2. Patients with a known genetic predisposition to colorectal cancer
3. Have had pre-sampling radiation therapy
4. Used antibiotics for at least 3 weeks prior to the study sampling

Healthy controls:

1. Individuals with a personal history of any cancer to maintain a cancer-free control group
2. Individuals with a family history of colorectal cancer in first-degree relatives
3. Used antibiotics for at least 3 weeks prior to the study sampling
4. Used antacid or PPIs drugs for at least 3 weeks prior to the study sampling

Date of first enrolment

16/10/2019

Date of final enrolment

16/05/2022

Locations

Countries of recruitment

Syria

Study participating centre

Tishreen University

Latakia

Syria

-

Study participating centre

Tishreen University Hospital

Latakia

Syria

-

Study participating centre

Atomic Energy Commission of Syria (AECS)

Damascus

Syria

-

Sponsor information

Organisation

Tishreen University

ROR

<https://ror.org/04nqts970>

Funder(s)

Funder type

University/education

Funder Name

Tishreen University

Alternative Name(s)

October University, Université Tichrine, , TU

Funding Body Type

Government organisation

Funding Body Subtype

Universities (academic only)

Location

Syria

Results and Publications

Individual participant data (IPD) sharing plan

All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary

Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/12/2024	17/12/2024	Yes	No
Protocol (other)		04/08/2023	29/08/2023	No	No