

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

<b>Submission date</b> 05/08/2023	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 29/08/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 17/12/2024	<b>Condition category</b> 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](mailto:abdulrahman.zuraik@tishreen.edu.sy)

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**EudraCT/CTIS number**  
Nil known

**IRAS number**

**ClinicalTrials.gov number**  
Nil known

**Secondary identifying numbers**  
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

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Community, Hospital, Laboratory

**Study type(s)**

Diagnostic, Other, Prevention, Screening, 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**

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 measure**

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

### **Secondary outcome measures**

There are no secondary outcome measures

### **Overall study start date**

16/05/2019

### **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

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Upper age limit**

80 Years

### **Sex**

Both

### **Target number of participants**

500

### **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

**Sponsor details**

Latakia

Latakia

Syria

-

+963-41-437480

inter-rel@tishreen.edu.sy

**Sponsor type**

University/education

**Website**

<http://en.tishreen.edu.sy/>

**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****Publication and dissemination plan**

Planned publication in a high-impact peer-reviewed journal

**Intention to publish date**

01/09/2023

**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?
<a href="#">Protocol (other)</a>		04/08/2023	29/08/2023	No	No
<a href="#">Results article</a>		01/12/2024	17/12/2024	Yes	No