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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	[_] Prospectively registered [X] Protocol
Registration date 29/08/2023	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 17/12/2024	**Condition category** Cancer	[_] 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?
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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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol (other)		04/08/2023	29/08/2023	No	No