Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effects of ischemia and tissue hypoxia in the pathogenesis of ulcerative colitis: a case control study

Protocol summary

Summary

Ulcerative colitis (UC) is a chronic mucosal inflammation which can affect any parts of colon but rectum is involved in the most of the cases. This disease characterized by bloody diarrhea, colicky abdominal pain, urgency and tenesmus.The main pathogenesis of this disease is already unknown. Many studies are focused on the role of abnormal mucosal immune responses to enteric bacteria triggered by environmental Factors. We conducted a randomised clinical trialPatients who took NSAIDs, vasodilators, corticosteroids (some studies showed they might affect tissue oxygenation) and patients with past medical history of ischemic heart disease, pulmonary disorders (COPD, asthma), severe anemia and vascular disease (vasculitis) and Diabetes which can cause tissue hypoxia were excluded. study to assess the role of ischemia in UC. 20 patients with UC, 20 people without any history of bowel disease and ten paraffin wax embedded tissue species from mesenteric ischemia and ten paraffin wax embedded tissue species include infectious colitis entered the study. Patient group underwent colonoscopy and endoscopy. Three samples were taken from the colon; one from ulcerative tissue, one from normal intestinal tissue and the last one from body of the stomach. Endoscopy and colonoscopy were also done for control group (they had referred for screening) with preparing one sample from colon and another from body of stomach. Systemic arterial blood gas sampling (ABG) was performed from radial artery after Allen testing. More over, perirectal capillary blood gas analysis using endoscopic ultrasound (EUS) with 100 cc normal saline and 80 mg gentamycine enema immediately before the procedure was performed. Thirty minutes after perirectal capillary blood gas was taken, blood culture was done to rule out bacteremia. Pathological species transferred to department of pathology for measuring HIF1a. Blood gas samples were assessed within 5 minutes in laboratory by pathologist, and results were recorded.Statistical analysis was done by the SPSS Statistics Data Document. (V 19.2) Differences among groups were determined using the general repeated ANOVA.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201208139736N1**
Registration date: **2012-08-21, 1391/05/31**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-08-21, 1391/05/31

Registrant information

Name
Seyed Amir Mirbagheri
Name of organization / entity
Tehran University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

The study was financially supported by university research center, Tehran University of Medical Sciences

Expected recruitment start date

2012-04-20, 1391/02/01

Expected recruitment end date

2012-10-22, 1391/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of ischemia and tissue hypoxia in the pathogenesis of ulcerative colitis: a case control study

Public title

Effects of ischemia and tissue hypoxia in the pathogenesis of ulcerative colitis: a case control study

Purpose

Diagnostic

Inclusion/Exclusion criteria

We conducted a randomised clinical trial study to assess the role of ischemia in UC. 20 patients with UC, 20 people without any history of bowel disease and ten paraffin wax embedded tissue species from mesenteric ischemia and ten paraffin wax embedded tissue species include infectious colitis entered the study. UC is diagnosed by clinical symptoms, sigmoidoscopy or colonoscopy findings and pathological species on biopsy.1Patients who took NSAIDs, vasodilators, corticosteroids (some studies showed they might affect tissue oxygenation) and patients with past medical history of ischemic heart disease, pulmonary disorders (COPD, asthma), severe anemia and vascular disease (vasculitis) and Diabetes which can cause tissue hypoxia were excluded. Control group included 10 people who were referred for screening with all the features mentioned above except history of clinical or colonoscopic bowel disease. Both group had the same age, sex and lived in the same height above the sea level.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical science

Street address

Tehran,Keshavarz Boulevard,pursina Aveniue

City

Tehran

Postal code

Approval date

2012-03-07, 1390/12/17

Ethics committee reference number

90-04-30-14993-52174

Health conditions studied

1

Description of health condition studied

Ulcerative Colitis

ICD-10 code

K51

ICD-10 code description

Ulcerative colitis

Primary outcomes

1

Description

Pericapillary Blood Gas

Timepoint

Before intervention and after intervention

Method of measurement

Laboratory data reports

2

Description

SystemicArterial Blood Gas

Timepoint

Before intervention and after intervention

Method of measurement

Laboratory data repots

3

Description

Tissue ischemic factors

Timepoint

Just after sampling

Method of measurement

Specila kits

Secondary outcomes

empty

Intervention groups

1

Description

Control group 1 included 20 people who are referred for screening with all the features of patients group except history of clinical or colonoscopic bowel disease.Endoscopy and colonoscopy will also apply for control group (they had referred for screening) with preparing one sample from colon and another from body of stomach. Systemic arterial blood gas sampling (ABG) is performed from radial artery after Allen testing. More over, Perirectal capillary blood gas analysis using endoscopic ultrasound (EUS) with 100 cc normal saline and 80 mg gentamycine enema immediately before the procedure is performed. Thirty minutes after perirectal capillary blood gas was taken, blood culture was done to rule out bacteremia .Lipid profile,CBC,FBS,EKGG and S/C was done for all of them.Pathological species transferred to department of pathology for measuring HIF1a. Blood gas samples were assessed within 5 minutes in laboratory by pathologist, and results were recorded.

Category

Diagnosis

2

Description

Control group 2:Ten paraffin wax embedded tissue species from mesenteric ischemia and ten paraffin wax embedded tissue species include infectious colitis entered the study.For this group just tissue ischemic factor by special kits will be assessed.

Category

Diagnosis

3

Description

Patients group interventions: Ten patients with Ulceratve Colitis are selected.Patients should be known case of UC and are diagnosed by clinical symptoms, sigmoidoscopy or colonoscopy findings and pathological species on biopsy.patients group will go under colonoscopy and endoscopy. Three samples are taken from the colon; one from ulcerative tissue, one from normal intestinal tissue and the last one from body of the stomach Systemic arterial blood gas sampling (ABG) are performed from radial artery after Allen testing. More over, Perirectal capillary blood gas analysis using endoscopic ultrasound (EUS) with 100 cc normal saline and 80 mg gentamycine enema immediately before the procedure was performed. Thirty minutes after perirectal capillary blood gas was taken, blood culture is done to rule out bacteremia .Pathological species transfer to department of pathology for measuring HIF1a. Lipid profile, CBC,FBS, S/C, EKG will be done for the patients.Blood gas samples شقثassessed within 5 minutes in laboratory by pathologist, and results were recorded

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Amira'lam hospital

Full name of responsible person

Dr Seyed Amir Mirbagheri

Street address

Tehran, Saadi Aveniue

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Faculty of Medicine, Tehran University of Medical science, Tehran, Iran

Full name of responsible person

Golband

Street address

Tehran, Keshavarz Boulvard, Poursina Aveniue

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Faculty of Medicine, Tehran University of Medical science, Tehran, Iran

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Faculty of Medicine, Tehran University of Medical science

Full name of responsible person

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty