

# Removal of the right side of the colon in emergency setting: indications and results

<b>Submission date</b> 21/03/2017	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 29/03/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 29/03/2017	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

A right hemicolectomy is a surgical procedure that removes the right side of the colon (bowels). Sometimes this has to be done in an emergency setting without the benefit of preparing the bowels for surgery (by removing waste from the bowels). There are a wide range of diseases and complications that affect parts of the colon such as inflammatory (swelling) or malignant (cancerous) diseases, perforation (ruptures of the bowels), obstructions (blockages), impaired circulation (blood flow) and trauma. Sometimes a surgeon is unable to diagnose the issue causing them to be unable to determine if the issue is malignant or not. In cases that the issue is caused by benign (non cancerous) diseases the surgeons have to decide between an ileocolic resection (which removes only the last part of the small intestine and the first part of the colon) and a right hemicolectomy, however there is no clear criteria for surgeons on how to make this choice. This causes performing right colectomies to be the preferred type of treatment. The aim of this study is to investigate if right hemicolectomies performed in an emergency setting impairs the quality of life of patients.

### Who can participate?

Adults aged 21 to 84 who require an emergency right hemicolectomy.

### What does the study involve?

Participants who have undergone an emergency right hemicolectomy are invited to participate in this study. Participants fill out a quality of life survey one month after their surgery during a follow up appointment. Participants are then followed up four months after surgery and complete a telephone interview. The questionnaire asks participants to think about their irritable bowel symptoms on their quality of life over the last two months. This is done to see if right hemicolectomies decrease the quality of life of participants.

### What are the possible benefits and risks of participating?

There are no notable benefits or risks with participating.

### Where is the study run from?

University Hospital "Alexandrovska" (Bulgaria)

When is the study starting and how long is it expected to run for?  
December 2011 to March 2017

Who is funding the study?  
Investigator initiated and funded (Bulgaria)

Who is the main contact?  
Dr Elena Arabadzhieva

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Elena Arabadzhieva

**Contact details**  
Medical University of Sofia  
1 Georgi Sofiiski Street  
Sofia  
Bulgaria  
1431

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
emrightthemicol\_QOL

## Study information

**Scientific Title**  
Emergency right hemicolectomy: Indications and functional outcomes

**Study objectives**  
The aim of this study is to evaluate if right hemicolectomy performed in emergency setting impairs the quality of life of patients.

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**  
The Ethical Committee of University Hospital "Alexandrovska", 23/01/2012, ref: N 3/23.01.2012

**Study design**

Observational cohort study

**Primary study design**

Observational

**Secondary study design**

Cohort study

**Study setting(s)**

Hospital

**Study type(s)**

Quality of life

**Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

**Health condition(s) or problem(s) studied**

Emergency right hemicolectomies

**Interventions**

Participants who have had an emergency right hemicolectomy are invited to participate in this study. Participants answer a quality of life questionnaire (measured with the validated IBS-36 questionnaire) during an examination at the end of the first month after the surgical procedure and through a telephone interview four months after the study. The questionnaire asks participants to think about their irritable bowel syndrome (IBS) symptoms on their quality of life over a two month time frame. The data collected from the questionnaires is then analysed by the research team. This is done to see if right hemicolectomies decrease the quality of life of participants.

Participants are followed up four months after their initial assessment by telephone and are resurveyed using the validated IBS-36 questionnaire.

**Intervention Type**

Behavioural

**Primary outcome measure**

Quality of life is measured using the validated questionnaire IBS-36 at baseline (one month after surgery) and month four.

**Secondary outcome measures**

Safety is measured using validated questionnaire IBS-36 at baseline (one month after surgery) and month four.

**Overall study start date**

05/12/2011

**Completion date**

03/03/2017

# Eligibility

## Key inclusion criteria

1. Patients requiring emergency right hemicolectomy
2. Aged 21 and 84

## Participant type(s)

Patient

## Age group

Mixed

## Sex

Both

## Target number of participants

24

## Key exclusion criteria

1. Malignant diseases
2. Patients who decline to participate

## Date of first enrolment

01/02/2012

## Date of final enrolment

31/12/2016

# Locations

## Countries of recruitment

Bulgaria

## Study participating centre

University Hospital "Alexandrovska"

1 Georgi Sofiiski Street

Sofia

Bulgaria

1431

# Sponsor information

## Organisation

University Hospital "Alexandrovska"

**Sponsor details**

1 Georgi Sofiiski Street  
Sofia  
Bulgaria  
1431

**Sponsor type**

Hospital/treatment centre

**ROR**

<https://ror.org/04b8y3f13>

**Funder(s)****Funder type**

Other

**Funder Name**

Investigator initiated and funded

**Results and Publications****Publication and dissemination plan**

Planned publication in a high-impact peer reviewed journal.

**Intention to publish date**

03/03/2018

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are/will be available upon request from Elena Arabadzhieva, [elena\\_arabadjieva@mail.bg](mailto:elena_arabadjieva@mail.bg) or [elena\\_arabadjieva@abv.bg](mailto:elena_arabadjieva@abv.bg)

**IPD sharing plan summary**

Available on request