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

Submission date 21/03/2017	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 29/03/2017	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 29/03/2017	**Condition category** Surgery	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol

Background and study aims
A right hemiocolectomy 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 investigative 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 hemiocolectomy.

What does the study involve?
Participants who have undergone an emergency right hemiocolectomy 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 or 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
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1431

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
emrighthemicol_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
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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 or elena_arabadjieva@abv.bg

IPD sharing plan summary
Available on request