

Primary repair of colon injuries: a clinical study of non-selective approach

Submission date 06/09/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 26/10/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 06/04/2011	Condition category Digestive System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Ranko Lazovic

Contact details
Clinical Center of Montenegro
Podgorica
Montenegro
81000
drlazovic@t-com.me

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Primary repair of colon injuries: a comparison between a retrospective group managed by primary repair or two stage procedure and a prospective group managed by primary repair without using exclusion criteria

Study objectives

Primary repair of colon injuries is possible in most cases without increased mortality and morbidity.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of Clinical Centre of Montenegro approved on the 2nd March 2002

Study design

Interventional randomised comparison between retrospective and prospective groups

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Screening

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

Colon trauma

Interventions

This study was designed as retrospective and prospective evaluation of primary repair procedures in colon trauma management. Retrospective (RS) group included 30 patients (25 males and 5 females) with colon injury, treated in the Clinical Centre of Montenegro (CCM), Podgorica, in period 1995 - 2000. All patients in this group had war injuries and in all cases selective approach was used for the decision about the method of repair. Prospective (PR) group included 33 patients (29 males and 4 females) managed by the same surgical team. In this group, exclusion criteria were not used, with intention for primary repair in every case.

Patients were followed up to 30 days and mortality and morbidity were recorded as primary and secondary end points.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Mortality, data collected 30 days after the operation

Secondary outcome measures

Morbidity, data collected 30 days after the operation

Overall study start date

01/01/1995

Completion date

31/12/2005

Eligibility

Key inclusion criteria

Patients greater than 18 years old (either sex) with colon injury

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

60

Key exclusion criteria

Patients less than 18 years old

Date of first enrolment

01/01/1995

Date of final enrolment

31/12/2005

Locations

Countries of recruitment

Montenegro

Study participating centre
Clinical Center of Montenegro
Podgorica
Montenegro
81000

Sponsor information

Organisation
Clinical Center of Montenegro (Montenegro)

Sponsor details
c/o Lazovic Ranko
Podgorica
Montenegro
81000
drlazovic@t-com.me

Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded trial (Montenegro)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	02/12/2010		Yes	No