PROTOCOL

DIVERTICULITIS MANAGEMENT: A SNAPSHOT COLLABORATIVE AUDIT STUDY

DAMASCUS

Protocol Version Number:	**DAMASCUS Protocol Version 3.0 28/09/2020**
Australia Protocol Version Number:	**DAMASCUS Protocol Version 3.0 28/09/2020 _Australia_ Version 5.0 28/09/2020**
Brazil Protocol Version Number:	**DAMASCUS Protocol Version 3.0 28/09/2020 _Brazil Version 6.0 28/09/2020**
Ireland Protocol Version Number:	**DAMASCUS Protocol Version 3.0 28/09/2020 _Ireland Version 6.0 28/09/2020**

Co-Chief Investigators: **Mr Dale Vimalachandran, Consultant Colorectal Surgeon, Chester, UK**

Professor Charles Knowles, Professor of Surgery, London, UK

Professor Tom Pinkney, Professor of Surgery, Birmingham, UK

CONTENTS

PROTOCOL CHANGES		
Date of change	**Protocol version number**	**Summary of change**
17-Dec-2019	**V2.0**	• **Clarification to eligibility criteria (age)** • **New section 'Patient Entry'** • **New section 'Statistical considerations'** • **New sub-section, 11.2 'Missing Data'** • **Clarification to section 12. Ethical Approval** • **Minor changes relating to typographical errors, corrections to grammar and consistent/correct use of terminology**
23-Jul-2020	**V2.1**	• **Reference to COVID-19 added to Section 8** • **Section 9.5 updated with revised estimated milestones** • **Minor administrative changes**
28-Sep-202	**V3.0**	• **Clarification to eligibility criteria (ambulatory patients), Section 8. Study Design, sub-section 9.3. Clinical outcomes, and sub-section 11. Data Management** • **Clarification to sub-section 13.1. Local Study Teams**

2. Abbreviations

ACPGBI	Association of Coloproctology of Great Britain and Ireland
ASA	American Society of Anaesthesiologists
ASCRS	American Society of Colon and Rectal Surgeons
BiSTC	Birmingham Surgical Trials Consortium
BMI	Body Mass Index
CI	Chief Investigator
CSSANZ	Colorectal Surgical Society of Australia and New Zealand
CT	Computed Tomography
DD	Diverticular Disease
DM	Diabetes Mellitus
ESCP	European Society of Coloproctology
GCP	Good Clinical Practice
IRAS	Integrated Research Application System
IRB	Institutional Review Board
i.v.	Intravenous
NELA	National Emergency Laparotomy Audit
PI	Principle Investigator
PIS	Patient Information Sheet
p.o	Per oral
SMG	Study Management Group

6. Signature Page

We the undersigned hereby approved the clinical audit protocol version 2.0, 20-Jan-2020

Signature  Date:20-Jan-2020

Name: Mr Dale Vimalachandran

Institution: Countess of Chester Hospital

Chief Investigator

Signature  Date: 20-Jan-2020

Name: Professor Charles Knowles

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4. Study Management Group

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5. Study Summary

Full Study Title	International, prospective snapshot collaborative audit of acute diverticulitis
Short Title	Diverticulitis Management: A Snapshot Collaborative Audit
Study Design	Multicentre, prospective audit
Study Duration	Approx. one year
Study Objectives	**Primary Objective** 1. Prospectively audit the national and international variability in the presentation and index management of acute diverticulitis; **Secondary Objectives** 2. What are the national and international variations in operating strategies employed for those patients undergoing surgery? 3. What are the international variations in 30-day mortality rates?
Study Outcomes	1. The short term clinical outcomes at 30-days (from index admission); 2. Readmission and/or re-intervention rates at 6-months (from index admission); 3. Clinical outcomes post radiological and/or surgical intervention; 4. If any patient- or disease-specific covariates affect treatment strategy or short term clinical outcomes; 5. Clinician equipoise for the recruitment of patients to future randomised controlled trials.
Coordinating Centre	Birmingham Surgical Trials Consortium
Collaborating Institutions	Association of Coloproctology of Great Britain and Ireland European Society of Coloproctology American Society of Colon and Rectal Surgeons Colorectal Surgical Society of Australia and New Zealand
Number of subjects	Approx. 4000

Eligibility Criteria	• Patients presenting with acute diverticulitis (newly incident within the audit period) • Adults (18 years and above) • Acute diverticulitis diagnosed either: - via multiplanar CT OR - during emergency surgery
Duration of data collection	Centres should collect data on eligible patients for 6 consecutive months. Each patient should be followed up for 6 months.

6. Introduction

Diverticular disease is a common problem affecting up to 65% of people aged over 80 [1]. Complications may affect 10-25% of these patients [2], and although some such as bleeding and inflammation can usually be managed conservatively, others such as perforation are more serious. Perforation may present as peritonitis requiring urgent surgery but can also occur in a more indolent fashion becoming sealed off, resulting in abscess formation.

The incidence of acute diverticulitis and hospital admissions for its complications are steadily increasing, not least due to a population cohort that exhibits the main risk factors for complicated diverticular disease (age and obesity). UK admission rates for acute diverticulitis increased from 0.56 to 1.20/1000/year between 1996 and 2006 along with a 2.28-fold increase in admissions for perforated disease, equating to approximately 12,000 emergency bowel resections/year [3].

Perforated disease has an associated short (8.2%) [4] and long-term mortality rate (14.5%) [4, 5], and these rates are particularly high in the UK. The exact cost to the NHS of this disease is unknown, but European and US studies have suggested direct and indirect costs range from £63 million to over £1 billion/year, respectively [6,7].

The broad initial management strategies for acute diverticulitis can vary from conservative strategies such as antibiotics and drainage procedures, through to more invasive surgical procedures such as laparoscopic lavage and bowel resection. Although there are a number of prospective studies advocating optimal treatment strategies, little is known about true clinical practice. Retrospective analysis of administrative dataset has suggested that there exists significant international variability in the index management of acute diverticulitis, and that such differences may contribute to the observed differences in mortality rates [4].

There are however very little prospective data regarding this perceived international variation, and furthermore there are specific subgroups of patients with acute diverticulitis such as diverticular abscess in which very little is known about the optimal management.

This study will audit the different types of management employed in patients presenting with acute diverticulitis. The aim is to explore whether an international variation in practice exists and if there is association between index management and short and medium term clinical outcomes only. From

this dataset, the variations in the index management and corresponding outcomes of patients with acute diverticulitis will be assessed.

This study will not investigate any patient reported outcomes, but it is hoped that the findings of this study will inform the design of future studies of acute diverticulitis which will collect patient level data.

7. Study Aims

7.1 Overall aims and design rationale

Little is known of the natural history and variation in strategies applied to managing acute diverticulitis. Furthermore, the feasibility of developing large scale, prospective interventional studies is also unclear due to the lack of baseline data regarding the incidence, initial management and outcomes of acute diverticulitis. The aim of this study is therefore to determine the international variability in disease management at index admission and to collect data that may inform the design of future studies. The large, global scale of this initial study will only allow the collection of short and medium term clinical data.

7.2 Primary Objective

1. To prospectively audit the national and international variability in the presentation and index management of acute diverticulitis;

7.3 Secondary Objectives

8 What are the national and international variations in operating strategies employed for those patients undergoing surgery?

9 What are the international variations in 30-day (post index admission) mortality rates?

7.4 Outcomes

1. The short term clinical outcomes at 30-days (from index admission);
2. Readmission and/or re-intervention rates at 6-months (from index admission);
3. Clinical outcomes post radiological and/or surgical intervention;
4. If any patient- or disease-specific covariates affect treatment strategy or short term clinical outcomes;
5. Clinician equipoise for the recruitment of patients to future randomised controlled trials.

8. Study Design

8.1 Overview

DAMASCUS is an international, multi-centre, prospective audit aiming to collect short term 30-day and 6-month clinical outcome data on the national and international variability in the presentation and management of acute diverticulitis.

Routine patient and clinical data will be recorded electronically (via the REDCap system) on bespoke CRFs. In light of the COVID-19 pandemic this audit will also seek to collect baseline demographic and initial management data relating to both patient and unit level COVID-19 status.

8.2 Setting

At least 80 acute general or university teaching hospitals, the study will be conducted across the Tripartite regions; UK, America, Australasia and Europe.

8.3 Target population

Adults attending hospital acutely with acute diverticulitis (CT proven or diagnosed during surgery for acute peritonitis) who undergo conservative, radiological or surgical treatment for their disease.

8.4 Eligibility criteria

8.4.1 Inclusion criteria

- Patients presenting with acute diverticulitis (newly incident within the audit period)
- Adults (18 years and above)
- Acute diverticulitis diagnosed either:
  - via multiplanar CT

    OR
  - during emergency surgery

NOTE:

- Patients who are admitted and require urgent surgery where the diagnosis is made either intra- or post operatively should be included in the audit
- Patients who have been admitted previously with acute diverticulitis should be included in the audit.
- Patients presenting with acute diverticulitis who are not admitted to hospital and are treated conservatively as ambulatory/outpatients should also be included in the audit.

8.4.2 Exclusion criteria:

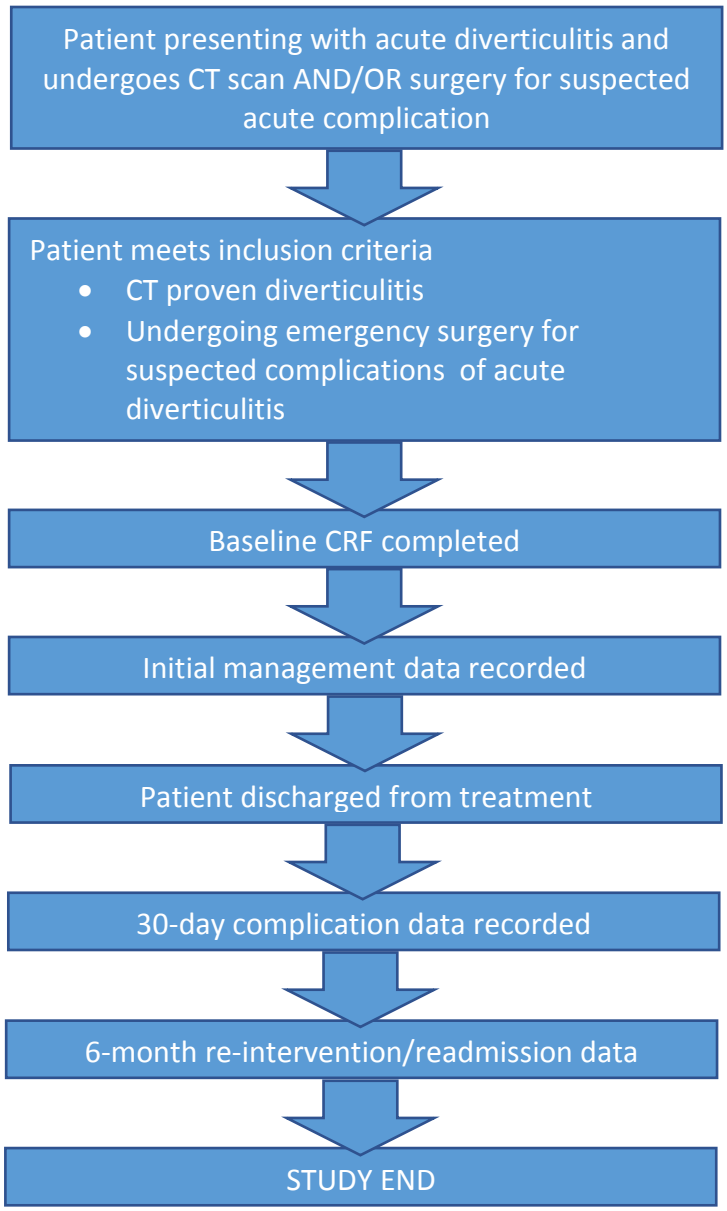
- Diagnoses other than diverticulitis

8.5 Interventions

The study is observational and low risk. There are no interventions and only routinely collected data will be used.

8.6 Patient Pathway and Identification

Within routine care, following confirmation of the diagnosis and eligibility, patient data can be included in the audit. Patients may present with a range of severities from relatively mild diverticulitis through to localised abscess formation or peritonitis. Consequently treatment may range from i.v. antibiotics, percutaneous drainage or surgery and these treatments may occur in single, combined or sequential regimens. Each treatment regimen will be recorded and if patients are readmitted within 6 months, data regarding any treatment or interventions will also be recorded. Patients who are admitted acutely with peritonitis and undergo emergency surgery without any form of imaging and are subsequently found to have acute diverticulitis should be included following surgery and/or pathological diagnosis



9. Data Collection

9.1 Patient Entry

Once eligibility is confirmed, the baseline CRF should be completed. When the data are uploaded onto the DAMASCUS REDCap database, a unique REDCap identifier will be allocated to the patient. This unique study number will be used in all correspondence between the DAMASCUS study office and the site. Linkage between the REDCap ID and patient should be maintained securely at hospital site.

9.2: Baseline data

Baseline data will be recorded at the index admission following confirmation of eligibility. Data will be collected by consultant surgeons, research fellows, surgical trainees, research nurses or a study co-ordinator. Electronic case report forms (incorporating baseline, 30-day outcome data and 6-monthly outcomes) will be used by the clinical care team to capture data on (a) the patient (fitness, frailty and main risk factors for disease recurrence [previous admissions, NSAID use[8] and obesity[9]; (b) the disease (including sepsis markers and CT findings); (c) the index management and any operative findings and strategy; (d) 30-day outcome (routine perioperative measures) and; (e) 6-month readmission/re-intervention rates. This CRF has been minimalised to facilitate rapid completion based on the principles embodied by other large scale studies in the emergency setting e.g. NELA [10]. **Only routine data will be collected, no additional information will be sought as this is an audit of practice only**.

9.3 Clinical outcomes

Data collected by clinical team at index admission, 30-day and 6- month follow up:

1. Main disease state and trait characteristics
2. Initial management at index presentation
3. Length of stay
4. Post-intervention complication rates
5. 30-day recurrent admission rate (as a surrogate marker of all health utilisation)
6. 30-day recurrent admission rate for diverticulitis and complications (as a surrogate of disease specific health utilisation)
7. 30-day recurrent intervention rate
8. 6-month readmission and/or re-intervention rate

9.4 Assessment of Clinician Equipoise

Future studies assessing the management of acute diverticulitis may need to be conducted as randomised trials, however it is known that such randomisation can be difficult due to lack of both clinician and patient equipoise. In order to assess this further within this audit, clinicians will be asked, as part of the index management CRF, whether they would in theory be prepared to recruit their patient to a study that may randomise treatment between conservative or surgical strategies.

9.5 Recruitment Projection

Emergency admissions for acute diverticulitis are increasing in the UK and are suspected to continue increasing year on year. Accurate figures for individual hospitals are difficult but in 2005/6 there were just under 24,000 in-patient admissions for acute diverticulitis [3]. It is anticipated that units will expect to admit on average 10 patients/month with acute diverticulitis, in practice the actual figure may be much lower or higher than this. Based on this estimation, with a recruitment base of 80 units globally, it is anticipated that up to 4,000 patients may be recruited over a 6 month period. We will however, be happy to exceed this number in terms of both number of centres and number of patients.

Estimated milestones are:

Pilot sites: January 2020

First patient recruited: October 2020

Last patient recruited: March 2020

Last follow up data collected: October 2021

10. Statistical Considerations

The statistical analysis of this international audit will be undertaken by our international management group including expert statisticians based within the Institute of Applied Health Research at the University of Birmingham. The report of the audit will be prepared in accordance with the guidelines as set by the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) statement for observational studies.

Continuous variables will be summarised with means and standard deviations; frequencies and percentages will be used for categorical variables. Univariate and multivariate analyses will be assessed by appropriate statistical techniques. Multilevel-logistic regression models will be used to allow for clustering at a centre or a country level. A p-value of <0.05 will be considered significant for all statistical methods used and the analysis will be completed using appropriate statistical software.

The performance of individual hospitals will not be disclosed and all subgroup analysis will include large patient cohorts to protect patient anonymity. No surgeon- or hospital-specific comparisons will be performed and analyses will only be reported at a country level for those in which at least 15 patients from a minimum of 3 hospitals have been included in the final dataset.

11. Data Handling and Record Keeping

11.1 Data Management

Data will be collected at the following times:

- During the index hospital presentation
- At 30 days after index admission, initial presentation and treatment as an outpatient, or emergency surgery for complications of acute diverticulitis
- At six months after index admission, initial presentation and treatment as an outpatient, or emergency surgery for complications of acute diverticulitis.

Data will be entered directly onto the DAMASCUS REDCap database by study collaborators at participating hospitals sites. REDCap [12, 13] is a secure, web-based software platform designed to support data capture of single and multi-site studies.

Site study collaborators will be provided with a paper copy of the eCRF to facilitate data collection. If this is used, they should then transfer data from the paper CRF to the online DAMASCUS database located at https://www.bistc.redcap.bham.ac.uk. DAMASCUS data management staff will check all incoming data CRFs for completeness, data consistency and compliance with the protocol. If discrepancies or missing data are identified, the DAMASCUS data management staff will raise queries with the research team at the participating hospital.

11.2 Missing Data

The online database has been designed to allow sites to securely access an individual patient's data for all CRFs throughout the study period. This means that any missing or erroneous data can be altered by the local investigators whilst the data collection period is ongoing. In order to maximise data completion and emphasise its importance to collaborators, participating centres with > 5% missing data in mandatory fields (i.e. < 95% data completeness) will be excluded from the study.

11.3 Data Security and Data Protection

The security of the study database system is governed by the policies of the University of Birmingham. The DAMASCUS study database will be hosted on the University's REDCap system managed and maintained by the BiSTC.

Data management and data security within the BiSTC will abide by the requirements of the General Data Protection Regulations (GDPR) and any subsequent amendments. The study will be conducted at collaborating sites in accordance with the country-specific data protection requirements. Data will be acquired and stored on the REDCap platform. Access to data will be restricted, each individual collaborator entering data for DAMASCUS will have their own username and password. Each participant will be allocated a unique study number at entry. All communication will use this as the identifier. All data will be analysed and reported in summary format. No individual will be identifiable.

11.4 Confidentiality

Patient identifiable information will not be collected in this study. All participant data held at the University of Birmingham will be anonymised.

All data collected about participants will be identified using only a unique DAMASCUS study number (REDCap ID). This number will be automatically allocated via REDCap once a new patient record is created in the DAMASCUS database.

Any correspondence between the DAMASCUS study office and hospital sites will use the DAMASCUS study number only.

The linkage between REDCap study ID and participants will be maintained in strict confidence at participating sites. This data will not be submitted to the DAMASCUS study office and will not be sent outside of the participating site.

Confidentiality of all participants' data will be maintained and there will be no disclosure of information by which participants may be identified to any third party other than those directly involved in the treatment of the participant. The participants will not by identifiable with regards to any future publications relating to this study.

12. Ethical Approval

In the UK, this study is categorised as an audit, not research (see Appendix I for the HRA decision tool outcome). Therefore, sites may participate once local clinical audit approval is in place.

Non-UK centres should seek advice from their local regulatory bodies (e.g. ethical committees) and apply for the required approvals, according to local, state or national policy, prior to study start. For centres in the US, surgeons must obtain Institute Review Board (IRB) approval prior to enrolling patients.

Only routinely collected data will be collected in the DAMASCUS study. Patients will not undergo any additional investigations or clinical follow-up for the study. No sensitive or identifiable data will be

collected on the REDCap database; the patient's clinical team will only upload anonymised data. We anticipate that most ethics review boards will waive the requirement for patient consent, as only anonymised audit data will be collected. However, there may be variation in international regulations and it will be the responsibility of the local principal investigators to seek local research ethics committee advice in each participating country to determine whether informed consent should be sought.

13. Study Administration

The study has been developed by an international study management team which will have at least two members from each Tripartite continent. This study management group will be chaired by the CI and further members from other countries will be added as appropriate.

The project will be under the auspices of the Chief Investigators and the Birmingham Surgical Trials Consortium. The project will be overseen by a Study Management Group (SMG).

13.1 Local Study Teams

Each participating centre will be responsible for identifying a PI,. Where feasible the use of trainee collaboratives will be encouraged to aid in the delivery of this study. The role of PI is to:

- Promote the study at site and facilitate delivery at site
- Liaise with the SMG
- Ensure that mechanisms for upload of data relating to eligible participants is in place
- Ensure appropriate local staff resources are maintained (cover provided for absence) to deliver the study

13.2 Patient and Public Development

The protocol has been developed in conjunction with patients and the public, and the SMG includes a lay member.

13.3 Publication Policy

The Chief Investigators will co-ordinate dissemination of data from this study. All publications using data from this study to undertake original analyses will be submitted to the SMG for review before release. The success of the study depends on a large number of clinicians. For this reason, credit for the results will not be given to the committees or central organisers, but to all who have collaborated and participated in the study. Acknowledgement will include all local co-ordinators and collaborators, members of the study committees, the SMG and administrative staff. Authorship at

the head of the primary results paper will be cited as a collaborative group to avoid giving undue prominence to any individual. All contributors to the trial will be listed at the end of the report, with their contribution to the study identified. Those responsible for other publications reporting specific aspects of the study may wish to utilise a different authorship model, such as "[name], [name] and [name] on behalf of the collaborative Group". Decisions about authorship of additional papers will be discussed and agreed by the study investigators and the SMG.

13.4 Dissemination of Research Findings

The results of this study will be submitted for publication in peer reviewed scientific journal, given the international nature of this study it is anticipated that this will be reflected in the journal selected. Results of the study will also be presented at meetings both national and international, according to the contributing nations. The findings of this study may be used to inform the design of further studies into diverticular disease.

13.5 Finance and Funding

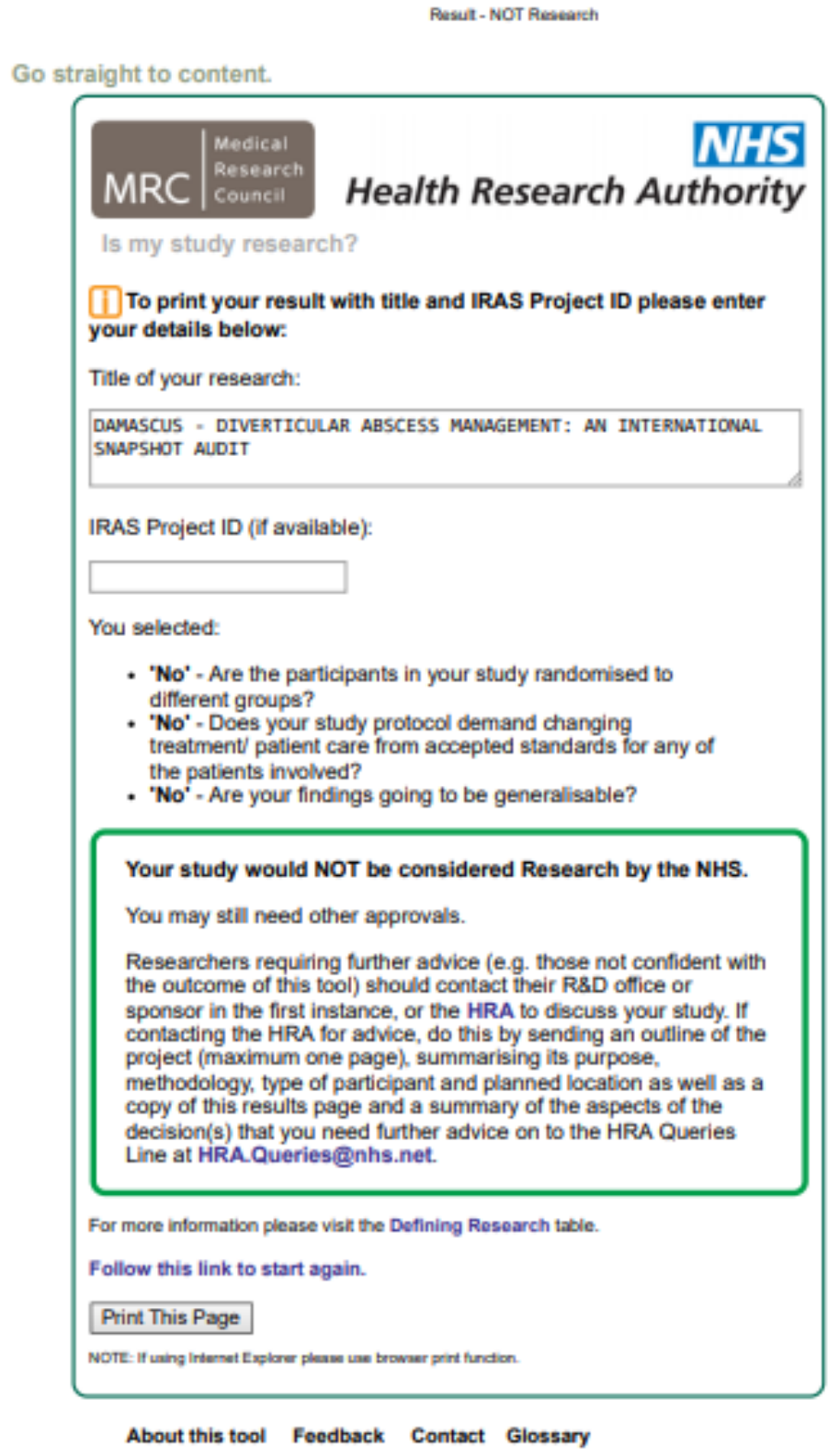
This study has been funded by the Bowel Disease Research Foundation in the United Kingdom. The study will be coordinated via Birmingham Surgical Trials Consortium and thus the burden of the cost will lie within the UK. Participating centres will not bear any costs for being part of this audit. Similarly, no financial reimbursement will be made to units or investigators for their involvement.

14. References

1. Munie ST, Nalamati SPM . Clin Colon Rectal Surg. Epidemiology and Pathophysiology of Diverticular Disease. 2018 Jul; 31(4):209-213.
2. L.B. Ferzoco, V. Raptopoulos, W. Silen. Acute diverticulitis. N. Engl. J. Med., 338 1998 1521-1526.
3. Jeyarajah S, Faiz O, Bottle A, Aylin P, Bjarnason I, Tekkis PP, Papagrigoriadis S. Diverticular disease hospital admissions are increasing, with poor outcomes in the elderly and emergency admissions. Aliment Pharmacol Ther. 2009 Dec 1; 30(11-12):1171-82.
4. Hong MKY, Skandarajah AR, Higgins RD, Faiz OD, Hayes IP. World J Surg. International Variation in Emergency Operation Rates for Acute Diverticulitis: Insights into Healthcare Value. 2017 Aug;41(8): 2121-2127.
5. Gregersen R, Andresen K, Burcharth J, Pommergaard HC, Rosenberg J. Long-term mortality and recurrence in patients treated for colonic diverticulitis with abscess formation: a nationwide register-based cohort study. Int J Colorectal Dis. 2018 Apr;33(4):431-440.
6. Mennini FS, Sciattella P, Marcellusic A et al. Economic burden of diverticular disease: An observational analysis based on real world data from an Italian region. Dig Liver Dis. 2017 Sep; (49):1003-1008.
7. Reddy VB, Longo WE. The burden of diverticular disease on patients and healthcare systems. Gastroenterol Hepatol 2013 Jan (9):21-27
8. You K, Bendl R, Taut C, et al. Randomized clinical trial of elective resection versus observation in diverticulitis with extraluminal air or abscess initially managed conservatively. Br J Surg. 2018;105(8):971-979.
9. Strate LL, Liu YL, Aldoori WH, Syngal S, Giovannucci EL. Obesity Increases the Risks of Diverticulitis and Diverticular Bleeding. *Gastroenterology*. 2009;136(1):115-122.e1. doi:10.1053/j.gastro.2008.09.025.
10. Peacock O, Bassett MG, Kuryba A, et al. Thirty-day mortality in patients undergoing laparotomy for small bowel obstruction. *Br J Surg*. 2018;105(8):1006-1013. doi:10.1002/bjs.10812.
11. Dindo D, Demartines N, Clavien P-A. Classification of surgical complications: a new proposal with evaluation in a cohort of 6336 patients and results of a survey. *Ann Surg*. 2004;240(2):205-213. http://www.ncbi.nlm.nih.gov/pubmed/15273542. Accessed February 9, 2018.
12. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG, Research electronic data capture (REDCap) – A metadata-driven methodology and workflow process for providing translational research informatics support, J Biomed Inform. 2009 Apr;42(2):377-81.
13. Harris PA, Taylor R, Minor BL, Elliott V, Fernandez M, O'Neal L, McLeod L, Delacqua G, Delacqua F, Kirby J, Duda SN, REDCap Consortium, The REDCap consortium: Building an international community of software partners, J Biomed Inform. 2019 May 9 [doi: 10.1016/j.jbi.2019.103208].

15. APPENDIX

HRA decision tool



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Is my study research?

To print your result with title and IRAS Project ID please enter your details below:

Title of your research:

DAMASCUS - DIVERTICULAR ABSCESS MANAGEMENT: AN INTERNATIONAL SNAPSHOT AUDIT

IRAS Project ID (if available):

You selected:

- **'No'** - Are the participants in your study randomised to different groups?
- **'No'** - Does your study protocol demand changing treatment/ patient care from accepted standards for any of the patients involved?
- **'No'** - Are your findings going to be generalisable?

Your study would NOT be considered Research by the NHS.

You may still need other approvals.

Researchers requiring further advice (e.g. those not confident with the outcome of this tool) should contact their R&D office or sponsor in the first instance, or the HRA to discuss your study. If contacting the HRA for advice, do this by sending an outline of the project (maximum one page), summarising its purpose, methodology, type of participant and planned location as well as a copy of this results page and a summary of the aspects of the decision(s) that you need further advice on to the HRA Queries Line at HRA.Queries@nhs.net.

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