



DIVERTICULAR ABSCESS MANAGEMENT: AN INTERNATIONAL SNAPSHOT

AUDIT

STUDY SUMMARY

What is the DAMASCUS study about?

DAMASCUS is an **audit** of the acute management of patients presenting acutely with diverticular abscesses. The study team are seeking to determine the international differences in the variation in index management and are also hoping to investigate whether these variations are associated with short term clinical outcomes at 30 days or with readmission or re-intervention rates over the subsequent 6 months.

Is this an audit or research?

DAMASCUS is an audit of clinical practice only, no patient specific or identifiable data will be collected. Outcomes will only concern clinical complications, readmissions or re-interventions that can be collected from patient's clinical notes.

Is ethical approval required?

In the UK the study can be run as an audit and does not require any patient consent or ethical approval (this has been confirmed with the Health Research Authority). In other countries ethical approval has been obtained in accordance to national guidance and patient's may be required to sign a consent form in order to collect their data.

How will data be collected and will it be anonymised ?

All data will be collected via the well established and secure RedCap server. All data will be anonymised.

Who will collect the data?

As this is a study of emergency patients, we anticipate that this is a study that will be primarily run by surgical trainees. However, in order to provide continuity to facilitate the 6-month notes review we do require a nominated consultant lead to be responsible for data collection in their unit.

What data will you be collecting?

We only require routine clinical data regarding patients' characteristics (eg. age, sex, co-morbidities), initial findings (CT, bloods) and initial management (eg. antibiotics, drain or



surgery). Follow up data will include any recorded complications in the first 30 days along with any readmissions or re-interventions in the subsequent 6-months following discharge. We will also seek to determine whether clinicians would have been prepared to recruit the patient to a hypothetical study of conservative treatment versus immediate or early surgical resection (pseudo-randomisation) and the reasons for their decision.

How many patients will be in the study?

We hope to recruit patients globally from across the world and to date have ethical approval and clinicians signed up to the study in the UK, USA, Europe, Australia and New Zealand. Our aim is to collect approximately 400 patients from across 80 units over a six month period.

Who is running the study?

The DAMASCUS study is sponsored by the Countess of Chester NHS Trust and is being conducted by the Birmingham Clinical Trials Unit. The study has been funded by the Bowel Disease Research Foundation.

What recognition will I receive for taking part?

Full credit and acknowledgement will be given to all those who take part in the study regardless of discipline or level. Full collaborative authorship will be used in any publications arising from the study and sites will be asked to confirm the names of all individuals that who participate in the study.

Who will be responsible for the study at each site?

We would ask that at each site a nominated consultant acts as the lead investigator given the 6 month follow up associated with the study. It is likely that trainees will rotate through a unit during the lifetime of the study and we would ask consultant leads to coordinate ongoing data collection.

How do I find out more about the study?

Further details and a copy of the protocol can be obtained from the CI (dale.vimalachandran@nhs.net), via the Dukes Club in the UK, the ESCP in Europe or the Birmingham Clinical Trials unit.

When does the study open?

We aim to open the study in October 2019 and run it for 6 months, the study will remain open for a further 6 months to complete all follow up data, closing in October 2020.

Can I get involved further in the study?



We would very much encourage anyone interested in becoming more involved to contact us. We would be extremely grateful if you could promote and advertise the study in your own local region and/or country.