Latin American Surgical Outcomes Study

Site Initiation

LASOS is a collaborative research study, multicentre and multicountry. Inclusivity and engagement of our local collaborators is the strength of this kind of study. We hope to contribute to a sustainable network for this and future research topics. However, to succeed in all large epidemiological studies, we need local collaborators to understand and engage with our objectives and methods to ensure good quality data. This way, all of us, our patients and our surgical health system can benefit from our efforts.

To start data collection in each hospital the following steps have to be followed:

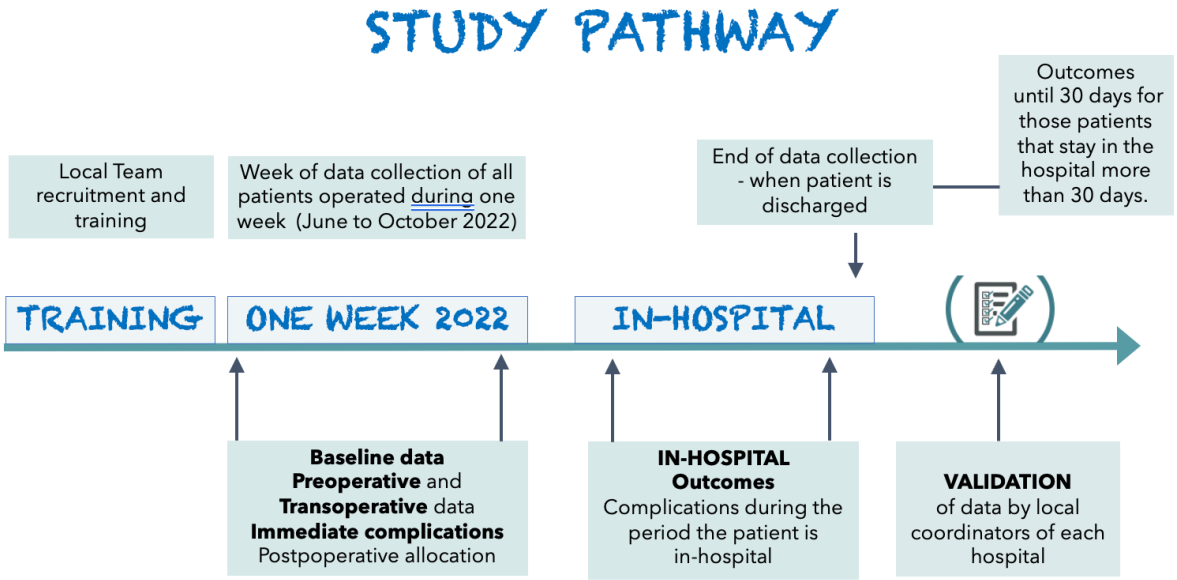
(1) Local coordinators of each hospital (Principal Investigator) will ensure that all relevant regulatory approvals are in place for their institution.
(2) Local coordinators will inform national coordinators general information about the hospital that will be included.

The following information of each hospital need to be provided: #university or non-university hospital #number of hospital beds #number of operating rooms #number and level of critical care beds #details about the reimbursement status of the hospital #university hospital status, #existence of residency in anesthesia, surgery, medicine or critical care #availability of a rapid response team #if the hospital holds valid accreditation (ONA, Qumentum or Joint Commission) and #the ratio of nursing staff to hospital beds in post-operative care areas.

(3) Local coordinators will find their institution on the website and they will register themselves as principal investigators. They will be authorized by the LASOS central administration and they will receive an e-mail with a password to access the database.
(4) Local team will register themselves in the website, after approval of the hospital, and their registration will be validated by the principal investigator of each hospital. We recommend that the local team participating includes anaesthetists and surgeons, if available.
(5) Local coordinators will act as guarantor for the integrity and quality of data collected.
(6) We strongly recommend a local teams training and the reading of the following documents available at the website:
Study protocol #Guidance for completing the CRF #Definiton of complications #Frequently Asked Questions # Database site training presentation (PDF presentation send by e-mail)

(7) Data will be collected in individual hospitals on a paper CRF for each patient recruited. Paper CRFs will be stored within a locked office in each centre. This will include identifiable patient data in order to allow follow-up of clinical outcomes. Specifically, for caesarean section, the CRF will be customised. Units for creatinine will be determined by the local coordinator at each hospital at the start of the study.

(8) Local investigator will mark the record as completed when all information regarding the following period is provided.



Frequent Asked Questions about data collection:

How do I find out the unique LASOS identifier code for my patient?

A unique code is created for each patient but not until you enter the data onto the internet based electronic case record form (eCRF).

Some patients will not have any blood tests requested (e.g. creatinine). Should we take blood samples so we can run these tests just for the study?

No. We do not want you to make any changes to the diagnostic tests or clinical treatment your patients would normally receive. If blood results are not available, please leave this domain empty.

What if the data requested is not available?

It is likely that some data such as blood results will not always be available. You should not order additional tests unless they are required for clinical reasons.

How is the duration of hospital stay defined in LASOS study?

Duration of hospital stay is defined as time in days from the day of surgery to the day the patient leaves your hospital. This will not be adjusted for delays relating to provision of social care.

What about patients who are still in hospital many months after surgery?

This will happen for a small number of patients. Because we need complete data entry quickly, we have decided to censor follow-up at thirty days. So all patients are followed until hospital discharge or for thirty days after surgery whichever is the shortest. If a patient remains in hospital after 30 days, please tick 'alive' to status at 30 days after surgery If the patient was discharged alive before day 30 please tick 'alive' and record number of days in hospital after the surgery. Day of surgery is a day zero, for instance if patient has had a surgery on Monday and was discharge on Wednesday, the total number of hospital stay after surgery is two.

We hope you get as enthusiastic about to start the project as we are. You can assess our website for study details. https://lasos-study.org/

Best regards,

LASOS Steering Committee

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