ISRCTN51817007 https://doi.org/10.1186/ISRCTN51817007

International Surgical Outcomes Study (ISOS)

Submission date 11/12/2013	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 03/01/2014	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 29/06/2021	**Condition category** Surgery	[_] Individual participant data

Plain English summary of protocol

Background and study aims
The findings of a recent study have suggested that deaths after surgery may be more frequent than previously thought, suggesting some may be preventable. However, there are limited available data describing complications, and therefore why patients die, following surgery. The aim of this study is to confirm the incidence of 30-day in-hospital complications following elective in-patient surgery.

Who can participate?
Adult patients aged 18 years or older undergoing elective surgery and staying overnight in hospital during the study period.

What does the study involve?
Participants will not receive any additional treatments or medicines as part of this study. Patients will be followed up for information describing outcomes after surgery until they leave hospital.

What are the possible benefits and risks of participating?
There are no risks of taking part and no changes to your treatment.

Where is the study run from?
The study is taking place in hundreds of hospitals around the world.

When is the study starting and how long is it expected to run for?
The study will take place during the spring of 2014.

Who is funding the study?
The study is funded by the Nestle Health Science SA.

Who is the main contact?
Professor Rupert Pearse - Chief Investigator
Marta Januszewska - Study Coordinator

Study website

http://www.isos.org.uk

Contact information

Type(s)
Scientific

Contact name
Prof Rupert Pearse

Contact details
Adult Critical Care Unit
Royal London Hospital
Whitechapel
London
United Kingdom
E1 1BB

Type(s)
Scientific

Contact name
Mr Richard Haslop

Contact details
Adult Critical Care Research Office
Room 14
Central Tower
Royal London Hospital
Whitechapel
London
United Kingdom
E1 1BB

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
International observational 7-day cohort study of complications following elective surgery

Acronym

ISOS

Study objectives
To confirm the incidence of 30-day in-hospital complications following elective in-patient surgery.

On 21/07/2015 the overall trial end date was changed from 01/04/2016 to 09/07/2014.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee Yorkshire & The Humber - Humber Bridge, 20/11/2013, REC ref: 13/YH/0371

Study design
International multicentre observational 7-day cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Patient information can be found at http://www.isos.org.uk/isos.php?page=docs

Health condition(s) or problem(s) studied
Elective surgery

Interventions
This is an observational study. Patients will be followed up until hospital discharge or for a maximum of 30 days, whichever is shorter.

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
To confirm the incidence of 30-day in-hospital complications following elective in-patient surgery.

Secondary outcome measures

1. In-hospital all-cause mortality (censored at 30 days following surgery)
2. Admission to critical care (within 30 days following surgery)
3. Duration of hospital stay (duration of primary hospital stay after surgery)

Overall study start date
01/04/2014

Completion date
09/07/2014

Eligibility

Key inclusion criteria
All adult patients (aged 18 years or older) undergoing elective surgery in a participating hospital during the seven-day cohort period with a planned overnight stay.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
50000

Key exclusion criteria
Patients undergoing emergency surgery, planned day-case surgery or radiological procedures

Date of first enrolment
01/04/2014

Date of final enrolment
09/07/2014

Locations

Countries of recruitment
Australia

Austria

Belgium

Brazil

Canada

China

Egypt

England

Germany

Greece

Hong Kong

India

Indonesia

Iraq

Italy

Malaysia

Mexico

New Zealand

Nigeria

Pakistan

Portugal

Romania

Russian Federation

Singapore

South Africa

Spain

Sweden

Switzerland

United Kingdom

United States of America

Study participating centre
Royal London Hospital
London
United Kingdom
E1 1BB

Sponsor information

Organisation
Queen Mary University of London (UK)

Sponsor details
Joint Research & Development Office
5 Walden Street
London
England
United Kingdom
E1 2EF

Sponsor type
University/education

Website
http://www.bartshealth.nhs.uk/research

ROR
https://ror.org/026zzn846

Funder(s)

Funder type
Industry

Funder Name
Nestlé Health Science SA.

Results and Publications

Publication and dissemination plan

We are currently in the process of revising the main study paper and considering options for submission. There will be secondary papers; however, we are currently focussing on the primary paper. The protocol has been published open access on the trial website (isos.org.uk). We will disseminate the findings publicly following publication of the main paper.

The study sponsor, Queen Mary University of London, has and will act as custodian of the data. In line with the principles of data preservation and sharing, the steering committee will, after publication of the overall dataset, consider all reasonable requests to conduct secondary analyses. The primary consideration for such decisions will be the quality and validity of any proposed analysis.

Only summary data will be presented publicly and all national, institutional and patient level data will be strictly anonymised. Individual patient data provided by participating hospitals remain the property of the respective institution. The complete ISOS dataset, anonymised with respect to participating patients, hospitals and nations, will be made freely and publicly available two years following publication of the main scientific report.

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	31/10/2016		Yes	No
Results article	India results	01/05/2021	29/06/2021	Yes	No
HRA research summary			28/06/2023	No	No