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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

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

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

Study type(s)
Treatment

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(s)
To confirm the incidence of 30-day in-hospital complications following elective in-patient surgery.

Key secondary outcome(s))
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)

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
United Kingdom

England

Australia

Austria

Belgium

Brazil

Canada

China

Egypt

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 States of America

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

Sponsor information

Organisation
Queen Mary University of London (UK)

ROR
https://ror.org/026zzn846

Funder(s)

Funder type
Industry

Funder Name
Nestlé Health Science SA.

Results and Publications

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes