

International Surgical Outcomes Study (ISOS)

Submission date 11/12/2013	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 03/01/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 29/06/2021	Condition category Surgery	<input type="checkbox"/> 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

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Additional identifiers

Protocol serial number

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

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