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# PRISM: prevention of respiratory insufficiency after surgical management

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| **Submission date**<br>03/02/2016 | **Recruitment status**<br>No longer recruiting | [X] Prospectively registered<br>[X] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>04/02/2016 | **Overall study status**<br>Completed | |
| **Last Edited**<br>22/06/2021 | **Condition category**<br>Respiratory | |

## Plain English summary of protocol

Background and study aims
Surgical complications are a major healthcare problem. Every year, around 310 million operations are carried out worldwide. After surgery more than 50 million patients will develop complications with more than three million deaths. The risk of illness or death following surgery is greatest for patients who have pre-existing medical conditions, are elderly or are undergoing surgery where the abdomen needs to be opened by the surgeon. Breathing problems, such as partial collapse of the lung and pneumonia, can be caused by the combination of surgery and anaesthesia, which in turn may lead to life threatening respiratory failure. Recent studies have shown that a type of oxygen delivery called continuous positive airway pressure (CPAP), where the lungs are kept inflated with a continuous supply of air (with extra oxygen) at a mild pressure, can help to reduce the number of serious breathing problems after abdominal surgery. The aim of the PRISM trial is to find out whether CPAP used for four hours immediately after surgery can help to reduce respiratory complications and increase 30 day and one-year survival rates compared to usual care in patients undergoing major abdominal surgery.

Who can participate?
Adults aged 50 years or over who are having open abdominal surgery by choice (elective).

What does the study involve?
Participants are randomly allocated to one of two groups. Participants in the first group receive the CPAP treatment for four hours immediately after surgery. This involves wearing a tight facemask or clear hood (helmet) that delivers a continuous supply of oxygen. The mask is attached to a pump which provides a flow of air in order to keep the airways open. Participants in the second group receive usual treatment, which may involve wearing a standard, looser fitting face-mask to provide oxygen after surgery. One month and then again one year after surgery all participants are contacted by telephone in order to find out about their recovery. Patient notes are also reviewed at this time in order to find out about the length of their hospital stay and details about any complications they may have had following surgery.

What are the possible benefits and risks of participating?
The risks of this trial to health are very small. CPAP is very safe, and has been used in hospitals for many years. Some patients even use this at home to help them sleep. Occasionally people

using CPAP can find the mask or hood uncomfortable, but small early studies suggest that CPAP should benefit most patients in this trial.

Where is the study run from?
The Royal London Hospital (UK), Sapienza University of Rome and University of Sassari (Italy)

When is the study starting and how long is it expected to run for?
May 2015 to December 2019

Who is funding the study?
1. National Institute for Health Research (UK)
2. Intersurgical Ltd (UK)
3. National Institute for Academic Anaesthesia (UK)

Who is the main contact?
Ms Mari-Liis Pakats
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### Study website
prismtrial.org

# Contact information

### Type(s)
Public

### Contact name
Ms Mari-Liis Pakats

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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
20252

# Study information

## Scientific Title
Prevention of Respiratory Insufficiency after Surgical Management (PRISM) Trial: a pragmatic randomised controlled trial of continuous positive airway pressure (CPAP) to prevent respiratory complications and improve survival following major abdominal surgery

## Acronym
PRISM

## Study objectives
The aim of this study is to determine whether early postoperative CPAP reduces the incidence of respiratory complications and improves one-year survival following major intra-peritoneal surgery.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
London - Central Research Ethics Committee, 02/10/2015, ref: 15/LO/1595

## Study design
International multi-centre randomised controlled trial with open study group allocation

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Other

## Study type(s)
Treatment

## Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

## Health condition(s) or problem(s) studied
Topic: Anaesthesia, perioperative medicine and pain management; Subtopic: Anaesthesia, perioperative medicine and pain management; Disease: All Anaesthesia, perioperative medicine and pain management

## Interventions
Following provision of informed consent, participants are randomly allocated to one of two groups using a computer generated dynamic procedure.

Intervention group: Following surgery, participants receive the continuous positive airway pressure (CPAP) intervention for at least four hours, after which the CPAP will be continued or discontinued at the clinician's discretion. The CPAP involves breathing through a pressurized circuit against a threshold resistor that maintains a pre-set positive airway pressure during both inspiration and expiration, through a face-mask, helmet or nasal device.

Control group: Following surgery, participants will receive usual care, managed by clinical staff according to local policy and guidelines.

Participants are followed up through medical record (paper or electronic) review and brief telephone interviews at 30 days and one year after surgery.

### Intervention Type
Other

### Primary outcome measure
Composite endpoint of pneumonia, endotracheal re-intubation or death, ascertained through review of patient notes and by patient telephone interview within 30 days of randomisation

### Secondary outcome measures
1. Pneumonia within 30 days of randomisation, ascertained through review of patient notes and by patient telephone interview within 30 days of randomisation
2. Endotracheal re-intubation within 30 days of randomisation, ascertained through review of patient notes and by patient telephone interview within 30 days of randomisation
3. Death within 30 days of randomisation, ascertained through review of patient notes and by patient telephone interview within 30 days of randomisation
4. Postoperative infection within 30 days of randomisation, ascertained through review of patient notes and by patient telephone interview within 30 days of randomisation
5. Mechanical ventilation (invasive or non-invasive), ascertained through review of patient notes and by patient telephone interview within 30 days of randomisation
6. All-cause mortality at one year after randomisation, ascertained by request hospital episode statistics and mortality data from the HSCIC for UK participants only. Prospective consent for ONS/HES data linkage will be sought before enrolment into the trial
7. Quality adjusted life years (QALY), ascertained by patient telephone interview using the EQ-5D (3L) questionnaire at one year after randomisation

### Overall study start date
01/05/2014

### Completion date
15/12/2019

## Eligibility

### Key inclusion criteria
1. Aged 50 years or over
2. Undergoing elective major intra-peritoneal surgery using an open surgical technique

### Participant type(s)
Patient

### Age group
Adult

### Sex
Both

### Target number of participants
Planned Sample Size: 4800; UK Sample Size: 2400; Description: The total sample size will be 4800 patients, recruited from several EU countries.

### Total final enrolment
4806

### Key exclusion criteria
1. Inability or refusal to provide informed consent
2. Anticipated requirement for invasive or non-invasive mechanical ventilation for at least four hours after surgery as part of routine care
3. Pregnancy or obstetric surgery
4. Previous enrollment in PRISM trial
5. Participation in a clinical trial of a treatment with a similar biological mechanism or related primary outcome measure
6. Clinician refusal

### Date of first enrolment
08/02/2016

### Date of final enrolment
15/12/2018

## Locations

### Countries of recruitment
England

Italy

United Kingdom

### Study participating centre
**The Royal London Hospital**
Whitechapel Road
London
United Kingdom
E1 1BB

### Study participating centre

**Sapienza University of Rome (Sapienza Universita di Roma)**
Piazzale Aldo Moro, 5,
Roma
Italy
00185

**Study participating centre**
**University of Sassari (Università degli Studi di Sassari)**
Piazza d'Armi, 17
Sassari SS
Italy
07100

# Sponsor information

**Organisation**
Barts & London School of Medicine

**Sponsor details**
Joint Research Management Office
5 Walden Street
London
England
United Kingdom
E1 2EF

**Sponsor type**
Hospital/treatment centre

**ROR**
https://ror.org/00b31g692

# Funder(s)

**Funder type**
Government

**Funder Name**
National Institute for Health Research

**Alternative Name(s)**

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

**Funding Body Type**
Government organisation

**Funding Body Subtype**
National government

**Location**
United Kingdom

**Funder Name**
Intersurgical Ltd

**Funder Name**
National Institute for Academic Anaesthesia

**Alternative Name(s)**
NIAA

**Funding Body Type**
Private sector organisation

**Funding Body Subtype**
Universities (academic only)

**Location**
United Kingdom

# Results and Publications

**Publication and dissemination plan**
Planned publication in a peer reviewed journal, conference presentations and webcasts. We intend to publish the main paper as soon as possible after completion of the trial.

**Intention to publish date**
15/12/2020

**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? |
|---|---|---|---|---|---|
| Protocol article | protocol | 01/02/2017 | | Yes | No |
| Results article | | 18/06/2021 | 22/06/2021 | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |