Servicio de Anestesiología, Reanimación y Terapéutica del Dolor

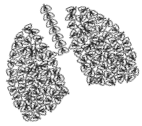
INCLIVA Instituto de Investigación Sanitaria

iPROVE-OLV

Individualized PeriopeRative Open lung Ventilatory stratEgy in patients submited to One Lung Ventilation (iPROVE-OLV): study protocol for an international multicenter randomized controlled trial.

Identifier	
HOSPITAL	
PATIENT IDENTIFICATION	
RESEARCHER 1	
RESEARCHER 2	

CONFIDENTIAL

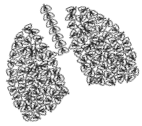


HOSPITAL		*SUBJECT*	

DEMOGRAPHIC DATA			
Age (years)		Height (cm)	
Gender	☐ Male ☐ Female	Weight (kg)	
Admission date		BMI (kg/m^2)	
Date of hospital discharge		Surgery date	
Informed consent obtention date		Randomization date	

Inclusion Criteria	**YES**	**NO**
Age equal to or older than 18 years	☐	☐
Thoracotomy or Video-assisted thoracic surgery (VATS) surgery scheduled for more than two hours of MV	☐	☐
Informed consent	☐	☐

Exclusion Criteria	**YES**	**NO**
Pregnancy or lactation	☐	☐
Participation on another medical trial or another experimental intervention protocol	☐	☐
BMI > 35 kg/m^2	☐	☐
ARDS (Acute respiratory distress syndrome) moderate or severe. PaO_2/FiO_2 < 200 mm Hg	☐	☐
Hemodynamic failure: Heart failure IC < 2,5 ml/min/m^2, use of inotropic drugs after surgery and/or heart failure diagnosis NYHA IV	☐	☐
Mechanical ventilation on the last 15 days due to acute or chronic pathology	☐	☐
Diagnosed or suspected Intracranial hypertension (intracranial pressure > 15 mmHg).	☐	☐
Pneumothorax. Giant bullae on chest X-ray or CT)	☐	☐
Previous lung resection	☐	☐



HOSPITAL		*SUBJECT*	

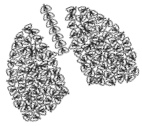
NOTE: If inclusion criteria were fulfilled, it will be obligatory to obtain the informed consent signed by the patient before the start of the clinical trial.

Surgery		
Procedure types		
□ Thoracotomy □ Thoracoscopy □ Thoracoscopic to Thoracotomy conversión		
Surgery types (approximate choice)		
□ Pneumonectomy	□ Lobectomy	
□ Bilobectomy	□ Segmentectomy	
□ Others		
¿Is it an oncologic surgery?		
□ Yes □ No		

PREOPERATORY DATA			
Diagnosis			
ASA			
□ I □ II □ III □ IV			
ARISCAT			
□ Moderate (26-44 puntos) □ High (> 44 puntos)			
SpO_2 (FIO_2 0.21)		Preoperatory Hb (g/dl)	
CHARLSON INDEX			
Total score:			
Lung infection on the last month			
□ Yes □ No			

Clinical background	**YES**	**NO**
High blood pressure	□	□

HOSPITAL		SUBJECT	



Ischemic cardiopathy	☐	☐
Diabetes mellitus type 1	☐	☐
Diabetes mellitus type 2	☐	☐
Smoker	☐	☐
Former smoker (> 3 month)	☐	☐
Alcohol consumption (more than two drinks per day)	☐	☐
Dyslipidemia	☐	☐
COPD (Chronic obstructive pulmonary disease)	☐	☐
Kidney failure	☐	☐
Hepatic failure	☐	☐
STOP-Bang Questionnaire		
Do you Snore Loudly (loud enough to be heard through closed doors	☐	☐
Do you often feel Tired, Fatigued, or Sleepy during the daytime	☐	☐
Has anyone Observed you Stop Breathing or Choking/Gasping during your sleep?	☐	☐
Do you have or are being treated for High Blood Pressure?	☐	☐
Body Mass Index more than 35 kg/m2?	☐	☐
Age older than 50?	☐	☐
Neck size large? (more than 40cm)	☐	☐
Male Gender?	☐	☐

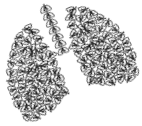
Treatment	**YES**	**NO**	**INDICATE**
Antibiotics on the last 3 months	☐	☐	
High blood pressure drug therapy	☐	☐	
Aspirin	☐	☐	
Statins	☐	☐	
Anti-diabetic medication	☐	☐	

HOSPITAL		SUBJECT	

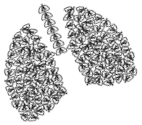
Insulin	□	□	
Inhalers	□	□	
Corticoid	□	□	
Chemotherapy before surgery?			
□ Yes □ No			
Radiotherapy before surgery?			
□ Yes □ No			

Preoperative pulmonary function test		
FVC (%):	FVC (L):	FEV1 (%):
FEV1 (L)	FEV1/FVC (%):	DLCO (%):
DLCO (mmol/min/kPa):	DLCO /VA (%)	VO_2max:
Residual volume (%):	Residual volume (L):	
Arterial gasometry		
pH:	PaO_2 (mmHg):	$PaCO_2$ (mmHg):

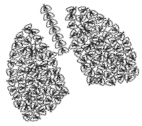
HOSPITAL		***SUBJECT***	



HOSPITAL		*SUBJECT*	



INTRAOPERATORY DATA					
	T0 Basal TLV (10 min after IOT)	**T1 Basal OLV** (After tube comprobation)	**T2 Basal OLV** (20 minutes start of OLV)	**T3 Final OLV**	**T4 Surgery ending** (pre-extubation)
PEEP (OL-PEEP) (mmHg)					
RR (respiratory rate)					
VT (ml)					
SpO_2 (%)					
FIO_2					
PaO_2 (mmHg)					
$PaCO_2$ (mmHg)					
pH					
Presión Pico (mmHg)					
Presión meseta (mmHg)					
Cdyn (ml/cmH_2O)					
PAM (mmHg)					
IC ($ml/min/m^2$)					



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Fluids (ml)			
Crystalloids		Packed red blood cells	
Colloids		Others	
Expected blood loss		Urinary output	

Additional information					
Duration of surgery (min)		Duration of OLV (min)		Duration of OLV + TLV (min)	

Surgical access

Right □ Left □

Use of vasoactive drugs (Not related to RM)

□ Yes □ No

Indicate:

Drugs	**Dose (mg)**
□ Noradrenaline	
□ Dobutamine	
□ Ephedrine	
□ Phenylephrine	

Anesthetic management

Hypnotic

□ Intravenous	□ Halogenated

Neuromuscular-blocking drug

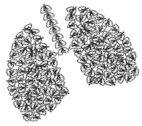
□ Cisatracurium	□ Atracurium
□ Rocuronium	□ Other. Indicate

RNM reversion?

□ Yes □ No

If yes, indicate which: □ Sugammadex □ Neostigmine

HOSPITAL		SUBJECT	



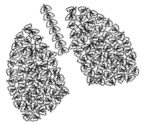
TOF Monitorization		
□ Yes □ No		
Analgesia		
□ Fentanyl	□ Sufentanil	
□ Remifentanil	□ Other (Indicate):	
Epidural (used during intraop)		
□ Yes □ No		
PONV prophylaxis		
□ Yes □ No		
If yes, indicate which		
□ Dexamethasone	□ Ondansetron	□ Other. Indicate
Antibiotic prophylaxis (60 minutes prior incisión)		
□ Yes □ No		
If yes, indicate which		

Recruitment maneuvers (RM)	**Crs** (ml/cmH_2O)	**OL-PEEP (**cmH_2O)
First RM		
Following RM **(If Crs drops ≥ 10%)**		
40 minutes □ Yes □ No, If yes indicate:		
80 minutes □ Yes □ No, If yes indicate:		
120 minutes □ Yes □ No, If yes indicate:		
160 minutes □ Yes □ No, If yes indicate:		
200 minutes □ Yes □ No, If yes indicate:		
240 minutes □ Yes □ No, If yes indicate:		
280 minutes □ Yes □ No, If yes indicate:		
320 minutes □ Yes □ No, If yes indicate:		

HOSPITAL		*SUBJECT*	

Incidental RM disconnection			
□ Yes □ No			
If yes indicate the number of performed maneuvers			
RM Failure			
First RM	□ Yes □ No	After ephedrine/phenylephrine administration	□ Yes □ No
Following RM	□ Yes □ No	After ephedrine/phenylephrine administration	□ Yes □ No
Intraoperative rescue maneuvers (see protocol criteria)			
□ Yes □ No			
Hypoxemia (SpO2<92%)			
□ Yes □ No			
If yes, indicate treatment			
□ TDL or BBq Correct collocation comprobation		□ Secretions aspiration	
□ Recruitment		□ CPAP	
□ Bilateral ventilation restoration		□ Others	

POSTOPERATIVE DATA
High-flow nasal cannula (iOLA-iHFNC group) (Only if SpO_2 <97% (FIO_2 0.21)
□ Yes □ No
Postoperative rescue maneuvers (see protocol criteria)
□ Yes □ No
If yes, indicate which:
NIV Invasive
Extubated patient in OR*
□ Yes □ No
If NO, reason:



HOSPITAL		SUBJECT	

□ Respiratory □ Hemodynamic □ Neurologic □ Others. Indicate:	
MV Time until extubation (min)	
Postoperative management according protocol?	
□ Yes □ No	
If NO, indicate the cause	
• (In case of no intraoperative extubation data from days 0, 1 and 3 will be collected after extubation. Data from days 7 and 30 (primary and secondary outcome) will be collected from the day of surgery)	
Analgesic control	
Analgesic	
□ Morphic chloride □ Fentanyl □ Other, indicate:	
Epidural	
□ Yes □ No	
Paravertebral	
□ Yes □ No	

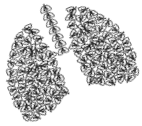
VAS (VAS evaluation will be done prior to the diagnose of atelectasis/hypoxemia)

Minutes after surgery	EVA	Drug dose
15		

NOTE: EVA level must be < 4 before “Air Test”

		Air Test
15-30 min after PACU	SpO_2	

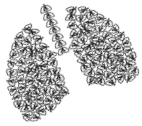
ADVERSE INCIDENTS It is considered an adverse incident when it appears directly related with MRA:
Haemodynamic inestability
□ Yes □ No
Arrhythmia and Haemodynamic inestability
□ Yes □ No



HOSPITAL		*SUBJECT*	

Pneumothorax
☐ Yes ☐ No

PROTOCOL NON FULFILLMENT
Intraoperative
Related to the specified ventilation protocol
☐ Yes ☐ No
If yes specify which:
Related to RM
☐ Yes ☐ No
If yes specify which:
Postoperative
Related to the Air-Test
☐ Yes ☐ No
If yes specify which:
Related to the NIV
☐ Yes ☐ No
If yes specify which:
Related to the ventilatory rescue maneuvers
☐ Yes ☐ No
If yes specify which:

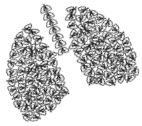


HOSPITAL		*SUBJECT*	

Observations

Postoperative gasometry (FIO_2 0.21) (After 6 hours in PACU)			
$PaCO_2$ (mmHg)		PaO_2 (mmHg)	
FIO_2		PaO_2/FIO_2 (mmHg)	
pH			
SpO_2 (FIO_2 0.21) (%) (After 6 hours in PACU)			

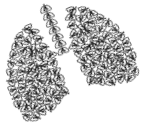
POSTOPERATIVE OUTCOMES	
Postoperative Complications	
DAY 0	
Does the patient have any complications on the 0 day after surgery?	
□ Yes □ No	
If yes, indicate the cause	
□ Mild acute respiratory failure	□ Severe acute respiratory failure
□ Lung infection	□ ARDS
□ Atelectasis requiring bronchoscopy	□ Pleural effusion
□ Bronchospasm	□ Contralateral pneumothorax to the surgical lung
□ Aspiration pneumonitis	□ Pulmonary embolism
□ COPD acute exacerbation	□ Bronchopleural fistula (with or without reintervention)



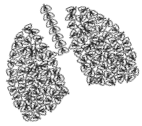
HOSPITAL		SUBJECT	

□ Pleural empyema (With or without reintervention)	□ Required rescue measures (CPAP, VMNI,VMI)
□ Reintubation	□ Atelectasis without bronchoscopy
□ Surgical site infection	□ Infections other than surgical site
□ *de novo* Atrial fibrillation	□ Sepsis
□ Myocardial ischemia	□ Acute kidney failure
□Septic shock	□ Hemothorax (with or without reintervention and/or transfusion)
DAY 1	
Does the patient have any complications on the 1 day after surgery?	
□ Yes □ No	
If yes, indicate the cause	
□ Mild acute respiratory failure	□ Severe acute respiratory failure
□ Lung infection	□ ARDS
□ Atelectasis requiring bronchoscopy	□ Pleural effusion
□ Bronchospasm	□ Contralateral pneumothorax to the surgical lung
□ Aspiration pneumonitis	□ Pulmonary embolism
□ COPD acute exacerbation	□ Bronchopleural fistula (with or without reintervention)
□ Pleural empyema (With or without reintervention)	□ Required rescue measures (CPAP, VMNI,VMI)
□ Reintubation	□ Atelectasis without bronchoscopy
□ Surgical site infection	□ Infections other than surgical site
□ *de novo* Atrial fibrillation	□ Sepsis
□ Myocardial ischemia	□ Acute kidney failure
□Septic shock	□ Hemothorax (with or without reintervention and/or transfusion)
DAY 3	
Does the patient have any complications 3 days after surgery?	

HOSPITAL		SUBJECT	



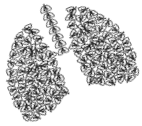
□ Yes □ No	
If yes, indicate the cause	
□ Mild acute respiratory failure	□ Severe acute respiratory failure
□ Lung infection	□ ARDS
□ Atelectasis requiring bronchoscopy	□ Pleural effusion
□ Bronchospasm	□ Contralateral pneumothorax to the surgical lung
□ Aspiration pneumonitis	□ Pulmonary embolism
□ COPD acute exacerbation	□ Bronchopleural fistula (with or without reintervention)
□ Pleural empyema (With or without reintervention)	□ Required rescue measures (CPAP, VMNI,VMI)
□ Reintubation	□ Atelectasis without bronchoscopy
□ Surgical site infection	□ Infections other than surgical site
□ *de novo* Atrial fibrillation	□ Sepsis
□ Myocardial ischemia	□ Acute kidney failure
□Septic shock	□ Hemothorax (with or without reintervention and/or transfusion)
DAY 7	
Does the patient have any complications 7 days after surgery?	
□ Yes □ No	
If yes, indicate the cause	
□ Mild acute respiratory failure	□ Severe acute respiratory failure
□ Lung infection	□ ARDS
□ Atelectasis requiring bronchoscopy	□ Pleural effusion
□ Bronchospasm	□ Contralateral pneumothorax to the surgical lung
□ Aspiration pneumonitis	□ Pulmonary embolism
□ COPD acute exacerbation	□ Bronchopleural fistula (with or without reintervention)



HOSPITAL		SUBJECT	

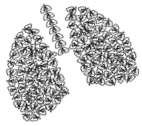
□ Pleural empyema (With or without reintervention)	□ Required rescue measures (CPAP, VMNI,VMI)
□ Reintubation	□ Atelectasis without bronchoscopy
□ Surgical site infection	□ Infections other than surgical site
□ *de novo* Atrial fibrillation	□ Sepsis
□ Myocardial ischemia	□ Acute kidney failure
□Septic shock	□ Hemothorax (with or without reintervention and/or transfusion)
DAY 30	
Does the patient have any complications 30 days after surgery?	
□ Yes □ No	
If yes, indicate the cause	
□ Mild acute respiratory failure	□ Severe acute respiratory failure
□ Lung infection	□ ARDS
□ Atelectasis requiring bronchoscopy	□ Pleural effusion
□ Bronchospasm	□ Contralateral pneumothorax to the surgical lung
□ Aspiration pneumonitis	□ Pulmonary embolism
□ COPD acute exacerbation	□ Bronchopleural fistula (with or without reintervention)
□ Pleural empyema (With or without reintervention)	□ Required rescue measures (CPAP, VMNI,VMI)
□ Reintubation	□ Atelectasis without bronchoscopy
□ Surgical site infection	□ Infections other than surgical site
□ *de novo* Atrial fibrillation	□ Sepsis
□ Myocardial ischemia	□ Acute kidney failure
□Septic shock	□ Hemothorax (with or without reintervention and/or transfusion)

Claven-Dildo classification (for the most serious complication)			
□ Grade I	□ Grade II	□ Grade III	□ Grade IV



HOSPITAL		*SUBJECT*	

ICU admission	
□ Yes □ No	
If yes, indicate the cause	
□ Programmed	□ Pulmonary
□ SIRS	□ Sepsis
□ Septic shock	□ Hemodynamic failure
□ Kidney failure	□ Multiorgan failure
□ Others. Indicate	
UCI discharge date	
ICU readmission?	
□ Yes □ No	
If yes, indicate the cause	
□ Multiorgan failure	□ Pulmonary
□ SIRS	□Sepsis
□ Septic shock	□ Hemodynamic failure
□ Kidney failure	□ Others. Indicate
Days of UCI readmission stay	
Reintervention (following 30 days to surgery)	
□ Yes □ No	
If yes, indicate the cause	
☐ Bleeding	☐ Wound dehiscence
☐ Infection	☐ Others (Indicate):
Hospital readmission (following 30 days to surgery)	
□ Yes □ No	



HOSPITAL		*SUBJECT*	

Survival	**Alive**	**Exitus**
Status at discharge	□	□
Status at 30 days post-surgery	□	□
Status at 180 days post-surgery	□	□
Status at 365 days post-surgery	□	□

Observations

Was the patient excluded from the study?
□ Yes □ No
If yes, indicate the cause
□ The patient revoked his consent
□ The surgical intervention is not performed
□ The patient meets some exclusion criteria
□ Others (Indicate which):

NOTE: At the end of the study, a copy of the CRD will be collected on paper completed and signed by the Investigator.