ANNEX 1 CASE REPORT FORM

FRAilty incidence in surGIcal European patients

European prospective cohort study of the prevalence of frailty in surgical patients.

Identifier	
HOSPITAL	
SUBJECT	
INVESTIGATOR	

CASE REPORT FORM (CRF)
Version 1.0 Date 25-February-2019

CONFIDENTIAL

Demographic Data	
Age (y/o):	Height (cm):
□ Male. □ Female	Weight (kg):
Date of admission (dd/mm/yyyy):	BMI (kg/m^2):
Date of hospital discharge (dd/mm/yyyy):	Date of surgery (dd/mm/yyyy):
Date of consent (dd/mm/yyyy):	Date of randomization (dd/mm/yyyy):

Inclusion criteria	**YES**	**NO**
18 years or older	□	□
Emergency or elective surgery under general anesthesia	□	□
Signature of informed consent to participate in the study	□	□

Exclusion criteria	**YES**	**NO**
Outpatient surgery	□	□
Obstetric analgesia or anesthesia	□	□
Organ transplant surgery	□	□
Cardiac surgery	□	□
Neurosurgery	□	□

NOTE: Once inclusion criteria are met, informed consent must be obtained before the start of the study.

Planned surgery	
Type of procedure:	
□ Elective	□ Emergency
Type of surgery (select the closest option)	
□Abdominal	□ Thoracic
□ Neurosurgery	□ Urologic
□ Gynecologic/Obstetric?	□ Trauma-Orthopedics
□ Vascular	□ Other
Type of Anesthesia	
□ General	□ Loco-regional
Oncologic surgery?	
□ Yes □ No	

BASELINE DATA					
Clinical background	**YES**	**NO**	**Clinical background**	**YES**	**NO**
blood pressure hypertension	☐	☐	Alcohol consumption (more than two drinks per day)	☐	☐
Ischaemic heart disease	☐	☐	Dyslipidemia	☐	☐
Diabetes mellitus type I	☐	☐	COPD (Chronic obstructive pulmonary disease)	☐	☐
Diabetes mellitus type II	☐	☐	Obstructive sleep apnea	☐	☐
Smoker	☐	☐	Kidney failure	☐	☐
Former smoker (≥ 3 months)	☐	☐	Hepatic failure	☐	☐
Previous treatment	**YES**	**NO**	**Previous treatment**	**YES**	**NO**
Antibiotics during the previous 3 months	☐	☐	Inhalers	☐	☐
Blood pressure medications	☐	☐	Corticosteroids	☐	☐
Aspirin	☐	☐	Benzodiazepines	☐	☐
Statins	☐	☐	Opioids	☐	☐
Oral antidiabetic drugs	☐	☐	Chemotherapy before surgery	☐	☐
Insulin	☐	☐	Radiotherapy before surgery	☐	☐

PREHABILITATION		
The intervention consists of a full-body physical exercise program. The evidence based protocol aims to improve the functionality of patients with or without frailty. The program may be performed at home or at the hospital on an outpatient basis for at least 4 weeks.	**YES**	**NO**
Physical exercise program	☐	☐
Nutritional education/ protein supplements / parenteral-enteral nutrition	☐	☐
Cognitive training	☐	☐

CLINCAL FRAILTY SCALE – Before surgery		
Very fit	Robust, active, energetic, motivated. Exercise regularly.	☐
Well	No active disease symptoms. Exercise or very active occasionally.	☐
Managing well	Well controlled medical problems. Not regularly active (walking).	☐
Vulnerable	Symptoms limit activities, but not dependent on others for daily help.	☐
Mildly frail	Evident slowing and need help in instrumental activities of daily living (controlling medication, finances, transportation, heavy housework). Typically impairs shopping, walking outside alone, meal preparation and housework.	☐
Moderately frail	Need help with all outside activities and housekeeping. Often have problems with stairs and need help with bathing and getting dressed.	☐
Severely frail	Completely dependent for personal care, any physical or cognitive activity. Stable, not at high risk of dying within 6 months.	☐
Very severely frail	Completely dependent, approaching the end of life. Typically, they could not recover from a minor illness.	☐
Terminally ill	Approaching the end of life. Life expectancy < 6 months.	☐

FRAIL QUESTIONNAIRE – Before surgery		
Affirmative response. 1-2 = Pre-frail; ≥3 = frail	**YES**	**NO**
Are you tired?	□	□
Are you unable to climb one flight of stairs?	□	□
Are you unable to walk one block?	□	□
Do you have more than 5 illnesses?	□	□
Have you lost 5% or more of your weight in the last 6 months?	□	□

BARTHEL INDEX – Before surgery			
Activity	Description	Score	
Feeding	1. Unable	0	□
	2. Needs help cutting, spreading butter, etc.	5	□
	3. Independent	10	□
Transfers	1. Unable, no sitting balance	0	□
	2. Major help, can sit	5	□
	3. Minor help	10	□
	4. Independent	15	□
Grooming	1. Needs help with personal care	0	□
	2. Independent face/hair/teeth/shaving	5	□
Toilet use	1. Dependent	0	□
	2. Needs some help, but can do something alone	5	□
	3. Independent	10	□
Bathing	1. Dependent	0	□
	2. Independent	5	□
Mobility	1. Immobile	0	□
	2. Wheelchair independent	5	□
	3. Walks with help of one person (verbal or physical)	10	□
	4. Independent at least 50m (but may use aid)	15	□
Stairs	1. Unable	0	□
	2. Needs help (verbal or physical)	5	□
	3. Independent up and down	10	□
Dressing	1. Dependent	0	□
	2. Needs help, but can do half unaided	5	□
	3. Independent	10	□
Bowel	1. Incontinent	0	□
	2. Occasional accident (once/week)	5	□
	3. Continent	10	□
Bladder	1. Incontinent or catheterized	0	□
	2. Occasional accident (once/day)	5	□
	3. Continent	10	□

CHARLSON INDEX- Before surgery							
Weight	**Condition**	**YES**	**NO**	**Weight**	**Condition**	**YES**	**NO**
1	Myocardial infarction	□	□	1	Liver disease, mild	□	□
1	Peripheral vascular disease	□	□	2	Cerebrovascular disease + disability	□	□
1	Dementia	□	□	2	Renal disease, AKI II-III	□	□
1	Chronic pulmonary disease	□	□	2	Diabetes with end organ damage	□	□
1	Ulcer disease	□	□	2	Cancer	□	□
1	Diabetes Mellitus	□	□	3	Liver disease, moderate or severe	□	□
1	Cerebrovascular disease	□	□	6	AIDS	□	□
1	Connective tissue disease	□	□	6	Metastatic malignancy	□	□

ASA PHYSICAL STATUS CLASSIFICATION SYSTEM		
ASA	**DEFINITIONS**	**EXAMPLES**
ASA I	A normal heathy patient	Healthy, non-smoking no or minimal alcohol use
ASA II	A patient with mild systemic disease	Current smoker, social alcohol, obesity (30<BMI<40), well-controlled DM/HTN, mild lung disease
ASA III	A patient with severe systemic disease	COPD, BMI>40, , alcohol dependence, moderate reduction of ejection fraction, CAD/stents, poorly controlled DM or HTN, active hepatitis…
ASA IV	A patient with severe systemic disease that is a constant threat to life	Sepsis, ongoing cardiac ischemia, severe valve dysfunction, severe reduction of ejection fraction,
ASA V	A moribund patient who is not expected to survive without the operation	Ruptured abdominal/thoracic aneurysm, massive trauma, intracranial bleed with mass effect, multiple organ/system disfunction.

Cognitive evaluation (Short Blessed Test) – Before surgery						
ITEM	**Test**	**Correct**	**Incorrect**	**Weight**	**Number of mistakes 0-5**	**Total**
1	What year are we in?	☐	☐	X4		
2	What month are we in?	☐	☐	X3		
3	Repeat the name and address: John Wayne, 3th avenue London	☐	☐	-		
4	What time is it?	☐	☐	X3		
5	Count back from 20 to 0	☐	☐	X2		
6	Count back the months of the year	☐	☐	X2		
7	Repeat the name and address: John Wayne, 3th avenue London	☐	☐	X2		
	Punctuation (0-28)					

EuroQOL-5D— Before surgery			
Mobility		**Pain/Discomfort**	
I have no problems in walking about	☐	I have no pain or discomfort	☐
I have some problems in walking about	☐	I have moderate pain or discomfort	☐
I am confined to bed	☐	I have extreme pain or discomfort	☐
Self-care		**Anxiety/depression**	
I have no problems	☐	I am not anxious or depressed	☐
I have some problems washing or getting dressed	☐	I am moderately anxious or depressed	☐
I am unable to wash or dress myself	☐	I am extremely anxious or depressed	☐
Usual activities			
I have no problems performing my usual activities	☐		
I have some problems performing my usual activities	☐		
I am unable to perform my usual activities	☐		

INTRAOPERATIVE DATA	YES	NO
Transfusion of blood components	☐	☐
Vasoactive drugs	☐	☐
Anesthetic depth monitoring	☐	☐
PERIOPERATIVE DATA		
Duration of surgery		min
Duration of mechanical ventilation (until extubation)		min

POSTOPERATIVE DATA	YES	Hours	NO
Admission to Post-Anesthesia Care Unit (PACU)	☐		☐
Planned ICU admission	☐		☐
Unplanned ICU admission	☐		☐
ICU readmission	☐		☐
Surgical reintervention when? During PACU stay?	☐		☐
Hospital re-admission (first 30 days)	☐		☐

POSTOPERATIVE DATA. Care bundles.	YES	Hours*	NO
Active mobilization			
Sitting on the bed	☐		☐
Sitting on a chair	☐		☐
Sitting	☐		☐
Walking	☐		☐
Nutrition			
Enteral	☐		☐
Parenteral	☐		☐
Oral liquids	☐		☐
Oral solid	☐		☐
Delirium screening	☐		☐
Cognitive dysfunction screening	☐		☐

***Hours since begins from the end of surgery. For delirium and cognitive dysfunction screening, the days after surgery when it is performed must be indicated.**

POSTOPERATIVE OUTCOMES			
Postoperative complications			
Does the patient have any complications 30 days after surgery?			
□ Yes □ No			
If the answer is yes, indicate the cause:			
□ Acute respiratory failure	□ Reintubation		
□ COPD exacerbation	□ ARDS		
□ Surgical wound infection	□ Pneumonia		
□ New onset atrial fibrillation	□ Acute pulmonary edema		
□ Myocardial ischemia	□ Acute kidney failure (KDIGO II-III)		
□ Septic shock	□ Sepsis		
□ Delirium	□ Cognitive dysfunction		
□ Paralytic ileus	□ Other (specify):		
Clavien-Dindo classification (for the most serious complication):			
□ Grade I	□ Grade II	□ Grade III	□ Grade IV

CLINCAL FRAILTY SCALE – 30 days after surgery		
Very fit	Robust, active, energetic, motivated. Exercise regularly.	□
Well	No active disease symptoms. Exercise or very active occasionally.	□
Managing well	Well controlled medical problems. Not regularly active (walking).	□
Vulnerable	Symptoms limit activities, but not dependent on others for daily help.	□
Mildly frail	Evident slowing and need help in instrumental activities of daily living (controlling medication, finances, transportation, heavy housework). Typically impairs shopping, walking outside alone, meal preparation and housework.	□
Moderately frail	Need help with all outside activities and housekeeping. Often have problems with stairs and need help with bathing and getting dressed.	□
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Terminally ill	Approaching the end of life. Life expectancy < 6 months.	□

FRAIL QUESTIONNAIRE – 30 days after surgery		
Affirmative response. 1-2 = Pre-frail; ≥3 = frail	**YES**	**NO**
Are you tired?	□	□
Are you unable to climb one flight of stairs?	□	□
Are you unable to walk one block?	□	□
Do you have more than 5 illnesses?	□	□
Have you lost 5% or more of your weight in the last 6 months?	□	□

BARTHEL INDEX – 30 days after surgery			
Activity	Description	Score	
Feeding	4. Unable	0	☐
	5. Needs help cutting, spreading butter, etc.	5	☐
	6. Independent	10	☐
Transfers	5. Unable, no sitting balance	0	☐
	6. Major help, can sit	5	☐
	7. Minor help	10	☐
	8. Independent	15	☐
Grooming	3. Needs help with personal care	0	☐
	4. Independent face/hair/teeth/shaving	5	☐
Toilet use	4. Dependent	0	☐
	5. Needs some help, but can do something alone	5	☐
	6. Independent	10	☐
Bathing	3. Dependent	0	☐
	4. Independent	5	☐
Mobility	5. Immobile	0	☐
	6. Wheelchair independent	5	☐
	7. Walks with help of one person (verbal or physical)	10	☐
	8. Independent at least 50m (but may use aid)	15	☐
Stairs	4. Unable	0	☐
	5. Needs help (verbal or physical)	5	☐
	6. Independent up and down	10	☐
Dressing	4. Dependent	0	☐
	5. Needs help, but can do half unaided	5	☐
	6. Independent	10	☐
Bowel	4. Incontinent	0	☐
	5. Occasional accident (once/week)	5	☐
	6. Continent	10	☐
Bladder	4. Incontinent or catheterized	0	☐
	5. Occasional accident (once/day)	5	☐
	6. Continent	10	☐

Cognitive evaluation (Short Blessed Test) – 30 days after surgery						
ITEM	**Test**	**Correct**	**Incorrect**	**Weight**	**Number of mistakes 0-5**	**Total**
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4	What time is it?	☐	☐	X3		
5	Count back from 20 to 0	☐	☐	X2		
6	Count back the months of the year	☐	☐	X2		
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	Punctuation (0-28)					

EuroQOL-5D— 30 days after surgery			
Mobility		**Pain/Discomfort**	
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I have no problems	☐	I am not anxious or depressed	☐

I have some problems washing or getting dressed	☐	I am moderately anxious or depressed	☐
I am unable to wash or dress myself	☐	I am extremely anxious or depressed	☐
Usual activities			
I have no problems performing my usual activities	☐		
I have some problems performing my usual activities	☐		
I am unable to perform my usual activities	☐		

Survival	**Alive**	**Dead**
At hospital discharge	☐	☐
30 days after surgery	☐	☐

ADMINISTRATIVE DATA	**YES**	**NO**		**YES**	**NO**
Extended ICU visit (> 10h)	☐	☐	Nurse ratio in ICU > 1/2	☐	☐
Physiotherapist in ICU	☐	☐	Nurse ratio in PACU > 1/4	☐	☐
Nutritionist in ICU	☐	☐	Nurse ratio in ward > 1/8	☐	☐

Was the patient excluded from the study?
☐ Yes ☐ No
If the answer is yes, indicate the cause:
☐ Patient withdraws consent
☐ Surgery was not performed
☐ Patient meets exclusion criteria
☐ Comments:

Signature:

Name and surnames: Date:

NOTE: At the end of the study, a paper copy of the completed CRF signed by the investigator will be collected