POSTOPERATIVE PHYSICAL REHABILITATION IN THE ELDERLY PATIENT AFTER EMERGENCY SURGERY.

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Research Article

Keywords: Rehabilitation, urgent general surgery, geriatric intervention, recovery of function, randomized controlled trial

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POSTOPERATIVE PHYSICAL REHABILITATION IN THE ELDERY PATIENT AFTER EMERGENCY SURGERY. INFLUENCE ON FUNCTIONAL, COGNITIVE AND QUALITY OF LIFE RECOVERY: study protocol for a randomized clinical trial.

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ABSTRACT

**Background:** The progressive aging of the population has meant the increase in elderly patients requiring urgent surgery. Older adults, especially those with frailty, have a higher risk for complications, functional and cognitive decline after urgent surgery. These patients have their functional and physiological reserve reduced which makes them more vulnerable to the effects of being bedridden. The consequences are at multiple levels emphasizing the functional loss or cognitive impairment, longer stays, mortality and institutionalization, delirium, poor quality of life and increased use of resources related to health.

We aim to determine whether postoperative physical rehabilitation can prevent functional and cognitive decline and modify the posterior trajectory.

**Methods/design:** This study is a randomized clinical trial, simple blinded, conducted in the Department of Surgery of a tertiary public hospital in Navarra (Hospital Universitario de Navarra), Spain. Patients $\geq 70$ years old undergoing urgent abdominal surgery who meet inclusion criteria will be randomly assigned to the intervention or control group. The intervention will consist of a multicomponent physical training program, which will include progressive and supervised endurance, resistance and balance training for 4 weeks; twice-weekly sessions with a total of 8 sessions, and the control group will receive the usual care. The primary outcome measure is the change in functional (Short Physical Performance Battery) and cognitive status (Mini-Mental State Examination) and the change of quality of life (EuroQol-SD-VAS) during the study period. The secondary outcomes are postoperative complications, length of stay, delirium, mortality, use of health resources, functional status (Barthel Index and Handgrip strength tests), cost per quality-adjusted life year and mininutricional assessment. The data for both the intervention group and the control group will be obtained at four different times: the initial visit during hospital admission and at months 1, 3 and 6 months after hospital discharge.

**Discussion:** If our hypothesis is correct this project could show that individualized and progressive exercise programme provides effective therapy for improving the functional capacity and achieve a better functional, cognitive and quality of life recovery. This measure, without entailing a significant expense for the administration, probably has an important repercussion both in the short and long terms recovery, improving care and functional parameters and could determine a lower subsequent need for health resources. To verify this, we will carry out a cost-effectiveness study.

The clinical impact of this trial can be significant if we help to modify the traditional management of the elderly patients from an illness model to a more person-centred and functionally oriented perspective. Moreover, the prescription of individualized exercise can be routinely included in the clinical practice of these patients.

**Trial Registration:** ClinicalTrials.gov Identifier: NCT05290532. Version 1. Registered on March 13, 2022.

**KEYWORDS**

Rehabilitation, urgent general surgery, geriatric intervention, recovery of function, randomized controlled trial.
BACKGROUND

The population in developed countries is rapidly aging, the number of Americans aged 65 years or older was 43 million in 2012 and this number is expected to be more than doubled by 2060 (1). The United Nations in its report "World Population Prospects 2019: Highlights" estimates that, in 2050, one in six people in the world will be over 65 years old (16%) (2). Specifically in Spain, in 2050, people over 65 will represent more than 30% of the total population and octogenarians will exceed four million (3). This rapid rate of population aging has been outpaced by an increase in number of older patients needing surgical intervention as a main modality of treatment (4-6).

There still exists lack of consensus about the definition of what age is considered the cut off for geriatrics (65 vs 70 vs 75 years old), there is consensus that patients should not be treated based on their age alone (7). However, there is evidence that age-related psychophysiological changes and co-morbidities affect older people’s tolerance to surgery, becoming a major life event with the risk of permanent and definitive disabilities (8). Frailty is a clinical syndrome defined by vulnerability and an increased risk of the individual to develop negative health-related events as disability and/or mortality under external stressors factors such as surgery (9). To identify older adults at high risk of numerous adverse outcomes five criteria have been established weight loss, exhaustion, leisure-time activity, gait speed and grip strength (10).

Related to this, quality of life has become one of the main health goals of the 21st century. Older adults consistently indicate that maintaining independent function is their top priority, more than 70% of the elderly would not choose a treatment that would lead to severe functional impairment, even if we ensured their survival (11–14). Hospital admission in these patients often leads to significant functional impairment, between 20 and 46% of patients have functional loss in one or more activities of daily life (11,15–17). Of these patients who present functional deterioration at discharge, recovery of the baseline situation is achieved in only 30% of them, most within the first month (18).

To reduce functional decline in older adults undergoing elective surgery, multimodal rehabilitation programs ERAS (Enhanced Recovery After Surgery) have been designed. Several previous studies, have included supervised exercises as multimodal rehabilitation, these programs aim to promote postoperative recovery in elective surgery. They have subsequently been extrapolated to urgent surgery proving that once adapted they are effective (19–21).

Focusing on the elderly patient undergoing surgery, the functional recovery is severely affected in the subgroup of patients who have required urgent surgery and in those with post-surgical complication (16,17,22). In urgent surgery patients, prehabilitation program cannot be performed, although, post-surgical rehabilitation is feasible. Rehabilitation based on physical exercise during admission in elderly patients after an acute process has shown an earlier recovery of their baseline functional status (23–28). However, there are few recommendations for rehabilitation programs including physical activity in older patients after urgent surgery.

We developed the first randomized clinical trial to assess the effectiveness of a rehabilitation program based on physical exercise during the first month after surgery.
The main objective of this study is to analyse whether postoperative physical rehabilitation in a short period of time improves functional and cognitive recovery and long-term quality of life (6 months) in elderly adults undergoing urgent abdominal surgery.
METHODS/DESIGN

Study design

This study is a randomized clinical trial conducted in the Department of Surgery of a tertiary public hospital in Navarre (Hospital Universitario de Navarra), Spain. Patients undergoing urgent abdominal surgery who meet inclusion criteria will be randomly assigned to the intervention or control group.

Patient recruitment will begin in the 4-day after the surgical procedure, these patients will be identified through the list of patients admitted to the hospital and assigned to the Department of General Surgery. Prior to randomization, the investigators will review the contraindications to participate in the exercise programme and will provide general information about the study. After signing an informed consent form, the subjects will be randomly.

Randomization will be performed by applying http://www.randomizer.org/. The doctor who decides the inclusion in the intervention or control group will not be the attending physician. Patients will be informed of the random inclusion in one of the groups.

The information in both groups is obtained in four different stages: the initial visit and at months 1, 3 and 6 after hospital discharge.

The protocol employs relevant standard protocol items for clinical trials according to the SPIRIT 2013 statement (29) and follows the CONSORT statement (29) for transparent reporting.

The trial is registered at ClinicalTrials.gov, identifier NCT05290532.

Study participants and eligibility criteria

Individuals ≥ 70 years old admitted to the Department of General Surgery of the Hospital Universitario de Navarra after an urgent surgery between March 2022 and March 2025.

The inclusion criteria are (Figure 1):
- Age 70 years and older.
- Undergoing urgent abdominal surgery.
- Able to ambulate, with or without personal / technical assistance or move unassisted in a wheelchair.
- Able to communicate: English or Spanish.
- Barthel Index >60.
- Informed consent: must be capable and willing to provide consent.

The exclusion criteria are (Figure 1):
- Severe dementia (GDS 7).
- Unwillingness to either complete the study requirements or to be randomized into control or intervention group.
- Unstable cardiovascular disease or other unstable medical condition.
- Myocardial infarction in the past 3 months.
- Terminal illness.
- Chronic kidney disease: dialysis.
- Upper or lower extremity fracture in the past 3 months.
- Evisceration.
- Patients transferred to a rehabilitation clinic prior to home discharge.

If the patient throughout the study presents any of the exclusion criteria or wishes to leave the study, they will be removed from the study.

**Randomization and blinding**

The study participants will be randomized into an intervention group and a control group following a simple randomization procedure with a 1:1 allocation through a computer system (www.randomizer.org) creating the allocation sequence with a block size of 20. The doctor who decides the inclusion in the intervention or control group will not be the attending physician and the assessment staff will be blinded to the participant randomization assignment. It will not be possible to conceal the group assignment from the staff involved in the training of the intervention group. Due to the nature of the study, patients may not be blinded as to the group to which they belong.

**Sample size and statistical analysis**

Assuming a type I error of 0.05, a correlation between pre and post-intervention values of the Short Physical Performance Battery (SPPB) of $r = 0.6$ and a standard deviation for the SPPB of 2.5, the required sample size to detect with a power of 90% a minimum difference of 1 point between groups in the change of SPPB score is 87 patients per group. Assuming losses of 20%, the final objective of the size of each group is 109 patients and, consequently, a total sample size will be 218 subjects. For the estimation, an ANCOVA method for the analysis of the differences has been considered. If the proportions of missing data are very large (more than 40%) on important variables, then trial results will be considered as hypothesis generating results.

Baseline values will compare by group using descriptive statistics as mean and standard deviation or median and interquartile range for quantitative variables and frequencies and percentages for categorical ones. To determine the efficacy of the intervention in the quantitative variables, such as the SPPB, we will use ANCOVA models, using post-intervention value as dependent variable, group study as the principal effect and pre-intervention value as covariate. If relevant group differences were observed at baseline, we would adjust for these variables in the model. In the case of qualitative or categorized variables (such as whether an improvement of a given magnitude between pre and post intervention has been achieved or not), comparisons between groups will be conducted with the chi-square test or Fisher’s test, and complemented with logistic regression if additional adjustment is needed.

The level of statistical significance will be 0.05. Data will be analysed using an intention-to-treat approach and using SPSS and R statistical software.

**Methods for further analysis**

Subgroup analyses will be performed to understand whether exercise is more or less effective according to age, type of surgery, comorbidity or hospital stay. These subgroup
analyses will follow the same plan as the primary analysis, as well as their interaction with the experimental condition.

**Plans for communicating important protocol amendments to relevant parties**

Ethical approval to conduct this study has been granted by the Hospital Universitario de Navarra Research Board (PI_2021/39). If relevant, current participants will be informed of protocol modifications. The ClinicalTrials.gov registry for this study will be updated with important protocol amendments.

**Data collection and management**

Completed personal data or other documents containing protected personal health information will be kept in a locked file at the principal investigator office in the Hospital Universitario de Navarra. Data will be entered into an electronic de-identified database by authorized study team members, and checked for completeness and accuracy. Access to data with identifiers will be restricted to authorized study team members and authorities. Identifiable data will be destroyed 10 years after study finalization or 5 years after last publication.

Adherence to training in the intervention group will be monitored by exercise trainers who will track attendance in training sessions. If participants miss any training sessions, they will be offered make-up sessions to complete the full 8 sessions of training. In both groups, in order to ensure attendance at the consultation, they are informed of the appointment by telephone and by letter.

**Detail description:**

Participants will be randomly assigned to the following groups:

- **Usual care group (control):**
  Participants randomly assigned to the usual care group will receive normal hospital care, including physical rehabilitation when needed.

- **Multicomponent exercise group (intervention):**
  The intervention will consist of a multicomponent physical training program (31), which will include progressive and supervised endurance, resistance and balance training for 4 weeks, twice weekly sessions with a total of 8 sessions.

  The supervised multicomponent exercise training program will be comprised of 5 minutes of endurance training on a cycle ergometer, followed by upper and lower body resistance exercises, tailored to the functional capacity of the individual, using weight machines and with the goal of 2-3 sets of 8-10 repetitions at an intensity of 40-60% of 1 maximal repetition (1RM) (Matrix, Johnson Health Tech, Ibérica, SL, Madrid, Spain) combined with balance exercises and stretching. Each resistance training session will include Chair Squat and Hip Abduction exercises, as well as training on variable resistance machines with two exercises for the lower extremities (leg press and knee
extension) and two exercises for the upper extremities (seated chest press and seated row). The training protocol is shown in Table 1.

**Table 1. Intervention group exercise**

<table>
<thead>
<tr>
<th>Exercise</th>
<th>Repetitions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Edurance training (Bicycle)</td>
<td>1 x 5</td>
</tr>
<tr>
<td>Chair squat</td>
<td>1 x 5</td>
</tr>
<tr>
<td>Leg press Machine</td>
<td>2 x 10</td>
</tr>
<tr>
<td>Chest press Machine</td>
<td>2 x 10</td>
</tr>
<tr>
<td>Leg extension Machine</td>
<td>2 x 10</td>
</tr>
<tr>
<td>Seated row Machine</td>
<td>2 x 10</td>
</tr>
<tr>
<td>Hip Abduction Exercises</td>
<td>2 x 5m</td>
</tr>
</tbody>
</table>

Study staff will collect all adverse events will be noted, which includes any event that occurs during or up to fifteen minutes, after intervention, and persists despite therapy interruption and constitute criteria for discontinuing intervention. Severe adverse events will be promptly reported to the Regional Ethics Committee of the HUN. Management of adverse effects will be based on participant protection and safety.

If participants desire to stop training or develop health conditions or injury that precludes safe participation of exercise over the course of the intervention, we will be exclude from the study.

Participants in either the intervention or control group will be asked to not participate in another structured exercise regimen or intervention over the course of their participation; otherwise, they will not be allowed to continue participation.

**Outcome measures**

- **Primary outcome**

The primary outcome measure is the change in functional and cognitive status and the change of quality of life during the study period. The functional capacity of patients will be evaluated by the Short Physical Performance Battery (SPPB) which combines, balance, gait ability, and leg strength using a single tool. The total score will range from 0 (worst)
to 12 points (best). The SPPB test has been shown to be a valid instrument for screening frailty and predicting disability, institutionalization, and mortality. The magnitude of meaningful change was one-point change in the score has clinical relevance. If the total score is less than 10 indicates frailty and a high risk of disability and falls.

The capacity will be assessed with the Mini-Mental State Examination (MMSE) (annex 2). This examination is composed of seven categories designed to assess specific cognitive functions: orientation to time (5 points), orientation to place (5 points), registration of three words (3 points), attention and calculation (5 points), recalling the three words (3 points), language (8 points) and constructive visual capacity (1 point). The MMSE score ranges from zero to 30 points, and lower values indicate possible cognitive deficit. Values from 27 to 30 denote preserved cognitive functions; from 24 to 26, changes that do not suggest deficit; from 20 to 23, changes that suggest cognitive deficit. Scores from 20 to 26 represent mild cognition impairments; between 11 and 20, moderate cognition impairment; and scores under 10 represent severe cognition impairments.

Changes in quality of life will be assessed by EuroQol-5D-VAS (annex 3). This is a generic health status questionnaire, consisting of five dimensions (mobility, self-care, usual activities, pain/discomfort, anxiety/depression) including three responses. It also includes a visual analogue scale for recording an individual’s rating of their current health-related quality of life (scale 0 to 100).

- **Secondary Outcome Measure:**
  - Postoperative complications: Clavien Dindo (annex 4) and Comprehensive Complication Index (annex 5).
  - Length of stay.
  - Delirium: Confusion Assessment Method (CAM) (annex 6).
  - Mortality: number of days alive after admission to the hospital.
  - Use of health resources: new admission to the hospital, admission to nursing homes, and visits to the general practitioner.
  - Functional status: Barthel index (annex 7).
  - Cost per quality-adjusted life year: both direct and indirect study participant costs.
  - Mininutricional Assessment short form (MNA-SF) (annex 8).
  - Handgrip strength test.
<table>
<thead>
<tr>
<th>ASSESSMENTS</th>
<th>DURING HOSPITAL ADMISSION</th>
<th>1 month</th>
<th>3 month</th>
<th>6 month</th>
</tr>
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<tbody>
<tr>
<td>SPPB</td>
<td>X</td>
<td>X</td>
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<td>X</td>
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<tr>
<td>Handgrip strength test</td>
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<tr>
<td>MMSE score</td>
<td>X</td>
<td>X</td>
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<tr>
<td>EuroQol-5D-VAS</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Barthel index</td>
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<tr>
<td>Mininutricional assessment short form</td>
<td>X</td>
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<tr>
<td>Confusion assessment method</td>
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<tr>
<td>Clavien Dindo</td>
<td>X</td>
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<tr>
<td>Comprehensive Complication Index</td>
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<td>Length of stay</td>
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<td>Use of health resources</td>
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<td>Mortality</td>
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<td>X</td>
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</tbody>
</table>

**Participant timeline**

The schedule of registration, interventions, evaluations and visits for the participants is shown in the following diagrams (figure 2).
OPPORTUNITY OF THE TRIAL/DISCUSSION

Functional decline and impaired quality of life are the main adverse outcomes of urgent surgery in the elderly patients. A high percentage of patients lose their autonomy, increasing the need for care at home and even the patient's institutionalization in a postoperative rehabilitation clinic. All this translates into a psychological impact for the patient and his or her environment and in a considerable unquantified increase in health spending.

All the current evidence from international organizations works reminds us that the most important thing in the elderly is to focus attention and health care on the maintenance of intrinsic capacity, that is, its functional capacity.

However, surgeons are focused on medical-surgical problems during hospitalization, being less attentive to functional recovery, which would require longer hospital stays and would greatly increase healthcare costs.

The rehabilitation program that we are proposing in this study could be applied in daily clinical practice, incorporating elderly patients undergoing urgent abdominal surgery into protocolized and standardized rehabilitation programs with postoperative physical activity.

An important aspect of our trial is the inclusion of elderly patients after an urgent abdominal surgery, the majority of trials with aged frail participants excluded the patients with a recent surgery, however, the surgery is a major factor in loss of functionality. This trial could demonstrate that a supervised multicomponent exercise training program adapted to each patient can be performed safely after emergency surgery and could improves functional results.

If our hypothesis is correct this project could show that individualized and progressive exercise programme provides effective therapy for improving the functional capacity and achieve a better functional, cognitive and quality of life recovery. This measure, without entailing a significant expense for the administration, probably has an important repercussion both in the short and long term, improving care and functional parameters and could determine a lower subsequent need for health resources. To verify this, we will carry out a cost-effectiveness study.

The clinical impact of this trial can be significant if we help to modify and shift the traditional management of this population from an illness model to a more person-centred and functionally oriented perspective. In this way, the prescription of individualized exercise could be routinely included in the clinical practice of these patients.
TRIALS STATUS
This is the first and definitive protocol version. Participants recruitment started in March 2022. We expect to finalize recruitment by December 2024 and complete the statistical analysis and publish the results by June 2025.

DISSEMINATION
The results of our study will be disseminated via presentations at international conferences and articles in peer-reviewed journals. The study will be implemented and reported in accordance with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines.

LIST OF ABBREVIATIONS
- Global Deterioration Scale (GDS)
- One maximal repetition (1RM)
- Short Physical Performance Battery (SPPB)
- Mini Mental State Examination (MMSE score)
- Confusion assessment method (CAM)
- Mininutricional assessment short form (MNA-SF)

DECLARATIONS
Ethics approval and consent to participate
Ethical approval to conduct this study has been granted by the Hospital Universitario de Navarra Research Board (PI_2021/39). Written informed consent to participate in this study will be obtained from all participants. The authors will provide a model consent form on request. Positive, negative, and inconclusive data will all be disseminated and published.

Availability of data and materials
All members of the Study group will have access to the anonymised, cleaned data set upon completion of the final post-intervention testing after approval from the steering committee.

Consent for publication
Not applicable.

Funding
This study has been funded by a Gobierno de Navarra project grant (resolución 1189/2021, del 23 de diciembre 2021).
**Role of the Funder/Sponsor**

The Gobierno de Navarra had no role in the design and conduct of the study.

**Conflicts of Interest**

The authors declare no conflict of interest.

**Authors' contributions**

The protocol was developed by Irene Esquiroz Lizaur, Ines Eguaras Córdoba and Fabricio Zambom-Ferraresi. Gregorio González Álvarez, Nicolás Martínez-Velilla and Ana Recreo Baquedano helped with participant recruitment and management. Iranzu Ollo-Martínez, Fabiola Zambom-Ferraresi and Antón De la Casa-Marín contributed to study conception and design, and project planning. Arkaitz Galbete Jimenez provided advice on the statistical analysis. Irene Esquiroz Lizaur, Ines Eguaras Córdoba and Fabricio Zambom-Ferraresi prepared the initial manuscript. All authors reviewed the final manuscript prior to submission. All authors read and approved the final manuscript.

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**Acknowledgements**

We thank our patients and their families for their confidence in the research team. We also thank Fundacion Miguel Servet (Navarrabiomed) for all its support during the implementation of the trial.
References


Figure 1. Inclusion and exclusion criteria, groups and follow up.

**Inclusion**
- Age $\geq$ 70 years and older.
- Undergoing urgent abdominal surgery.
- Able to ambulate, with or without personal / technical assistance or move unassisted in a wheelchair.
- Able to communicate: English or Spanish.
- Barthel Index $>60$.
- Informed consent: must be capable and willing to provide consent.

**Exclusion**
- Severe dementia (GDS 7)
- Hospitalization $<4$ days
- Unstable cardiovascular disease or other unstable medical condition.
- Myocardial infarction in the past 3 months.
- Terminal illness.
- Chronic kidney disease: dialysis.
- Upper or lower extremity fracture in the past 3 months.
- Evisceration.

**Intervention Group**
4 weeks of rehabilitation

**Control Group**
No rehabilitation

Follow-up: at months 1, 3 and 6 after hospital discharge.
Recruiting participants among urgent surgery patients (aged ≥70 years)

Assessment for eligibility

Explanation of the study and informed consent

Inclusion and Randomization (n:218)

Training group

Control group

Follow-up at discharge (1 month)

Follow-up at discharge (3 month)

Follow-up at discharge (6 month)
Annex 1: Informed consent material

Hoja de Información a los Participantes y el Consentimiento Informado

TÍTULO DEL ESTUDIO: REHABILITACIÓN FÍSICA POSTOPERATORIA EN EL PACIENTE ANCIANO TRAS CIRUGÍA URGENTE. INFLUENCIA EN LA RECUPERACIÓN FUNCIONAL, COGNITIVA Y DE CALIDAD DE VIDA.

Investigador responsable: Irene Esquiroz Lizaur, Facultativo especialista del Área de Cirugía General y del Aparato Digestivo. Unidad de Cirugía Colorrectal. Área de Cirugía General del Complejo Hospitalario de Navarra.

Apreciado Sr./A

Solicitanos su participación en este estudio de investigación, que se lleva a cabo en el Complejo Hospitalario de Navarra. El principal objetivo del estudio es analizar si la rehabilitación física postoperatoria en un corto período de tiempo, influye en la recuperación funcional, cognitiva y de la calidad de vida, en los pacientes ancianos intervenidos de cirugía abdominal urgente.

Antes de confirmar su participación en este estudio de investigación, es importante que entienda en qué consiste. Por favor, lea detenidamente este documento y haga a su médico todas las preguntas que le puedan surgir.

HOJA DE INFORMACIÓN

1-Descripción del estudio

A través de esta hoja informativa se le invita a participar en un estudio de investigación realizado en personas mayores o iguales de 70 años que son intervenidos de cirugía abdominal urgente.

En este estudio pretendemos comprobar si un programa adaptado de ejercicio físico postoperatorio mejora la recuperación funcional, cognitiva y de la calidad de vida, en los pacientes ancianos intervenidos de cirugía abdominal urgente.

Si usted desea participar, se le evaluará a partir de varias herramientas de valoración funcional, cognitiva y de calidad de vida, que consistirán en la realización de varios cuestionarios y una prueba física en la que se le solicitará realizar movilizaciones como levantarse de una silla o caminar 4 metros.

Tras esta valoración inicial usted pasará a formar parte del grupo intervención o del grupo control de manera aleatoria. Si pasa a formar parte del grupo intervención, completará un programa de ejercicio físico personalizado. Este consistirá en una sesión diaria de 45 minutos, dos veces por semana, durante 4 semanas consecutivas. Un especialista en ejercicio experimentado supervisará la sesión de cada paciente y proporcionará instrucciones. Las sesiones consisten en ejercicios individualizados y supervisados de entrenamiento anaeróbico (bicicleta), fuerza y equilibrio. Tras estas 4 semanas, se volverá a realizar una nueva
valoración funcional, cognitiva y de calidad de vida que se repetirá en la consulta a los 3 y 6 meses. La duración aproximada de cada consulta será de unos 20-30 minutos.

En caso de que tras aleatorización pase a formar parte del grupo control recibirá los cuidados habituales en el postoperatorio y se realizará el mismo seguimiento que en el grupo intervención. Seguimiento en consulta con evaluación funcional, cognitiva y de la calidad de vida al 1º, 3º y 6º mes.

2-Riesgos y Beneficio

No vamos a probar la eficacia de ningún medicamente nuevo. La intervención consiste en un protocolo de rehabilitación funcional. Estos protocolos se han estudiado en otras poblaciones donde han mostrado beneficio para el paciente y ausencia de aumento de las complicaciones. En este estudio, intentamos confirmar si los resultados de estos trabajos podrían aplicarse a la población del Complejo Hospitalario de Navarra.

Durante la realización de ejercicio físico es posible que tenga cansancio o molestias propias de la práctica de ejercicio. En caso de aparición de síntomas que supongan un riesgo para para el paciente se interrumpirán los ejercicios y se informará a su médico responsable.

3-Participación voluntaria

Debe saber que su participación en este estudio es totalmente voluntaria. Usted puede negarse a participar en él o abandonar el estudio en cualquier momento sin que ello se vea afectada su atención médica y se seguirán los protocolos habituales.

4-Confidencialidad: ¿Cómo se van a utilizar mis datos del estudio?

Si usted accede a participar en este estudio, se le pedirá por parte del equipo investigador el acceso a sus datos grabados el programa de Historia Clínica Informatizada.

Toda la información que se obtenga durante este estudio será confidencial y ni usted ni sus datos estarán identificados en cualquier informe que se emita de este estudio. Estos datos se manejarán de acuerdo con la Ley Orgánica de Protección de Datos Personales del 5 de diciembre de 2018, y el Reglamento (UE) 679/2016 del Parlamento Europeo y del Consejo del 17 de abril de 2016 de Protección de Datos (RGPD). Este tiene derecho a ejercer el control de sus datos personales, es decir, tiene derecho acceder, modificar, cancelar o negarse a su uso dirigiéndose al investigador principal o cualquier miembro del equipo investigador.

Los datos obtenidos se guardarán en una base de datos de acceso restringido a los investigadores que participan en el estudio, ubicada en un despacho del Servicio de Cirugía General que el investigador principal del estudio, Irene Esquiroz, custodiará.

El/la doctor/a del estudio y su equipo investigador, podrá utilizar los datos recogidos en el estudio para la difusión de resultados dentro de la comunidad científica y garantizará la protección de estos datos a fin de no desvelar su identidad. Únicamente el equipo investigador, tendrán acceso a la clave del código que permite asociar los datos del estudio con su identidad.
Debe usted saber también que para que este estudio pueda ser realizado, previamente ha debido ser autorizado por el investigador principal y el comité de ética de investigación clínica de su Hospital.

Si lo desea puede solicitar a su médico más información o aclaración sobre el estudio. Recuerde que puede retirarse del estudio en cualquier momento, sin que ello suponga una alteración de sus relaciones con el equipo investigador.

5. ¿Cómo puedo establecer contacto si tengo dudas o necesito obtener más información?

Mediante la firma de este formulario, usted asiente que ha estado informado de las características del estudio, ha entendido la información y el/la doctor/a ha clarificado todas sus dudas.

Puede pedir más información o solucionar cualquier duda sobre su participación en este o cualquier momento a lo largo del estudio contactando con el Dra. Irene Esquiroz Lizaur del Complejo Hospitalario de Navarra.

Nombre del Investigador Principal:
Dra. Irene Esquiroz Lizaur
Email: irene.esquiroz.lizaur@navarra.es
Unidad Cirugía General y del Aparato Digestivo
C/ Irunlarrea nº 3, 31008, Pamplona (Navarra)
Hoja de Información a los Participantes y el Consentimiento Informado

TITULO DEL ESTUDIO: REHABILITACIÓN FÍSICA POSTOPERATORIA EN EL PACIENTE ANCIANO TRAS CIRUGÍA URGENTE. INFLUENCIA EN LA RECUPERACIÓN FUNCIONAL, CÓGNITIVA Y DE CALIDAD DE VIDA.

Investigador responsable: Irene Esquiroz Lizar, Facultativo especialista del Área de Cirugía General y del Aparato Digestivo. Unidad de Cirugía Colorrectal. Área de Cirugía General del Complejo Hospitalario de Navarra.

CONSENTIMIENTO INFORMADO

Declaro que:
1. He leído la “Hoja de información al paciente”, entiendo los objetivos del estudio y estoy dispuesto a participar en su realización acudiendo a evaluaciones periódicas.
2. He sido informado y entiendo que los miembros del equipo investigador podrán utilizar información de carácter personal recogida en la historia clínica informatizada para confirmar mi idoneidad y completar los datos necesarios para poder formar parte de la Base de Datos del ensayo clínico.
3. Entiendo que mi participación es voluntaria y que tengo el derecho a abandonar el estudio en el momento que lo desee una vez iniciado.
4. He podido aclarar todas mis dudas respecto a los objetivos del estudio.

En ________________, a ____________ de ____________
Firma investigador: ____________________________
Nombre y apellidos del paciente: ____________________________
Nº Colegiado: ____________________________
Firma: ____________________________

Autorización por representación. -El consentimiento podrá ser otorgado por su representante legal o persona vinculada por razón familiar o de hecho, en caso de voluntad del/la paciente o incapacidad del paciente, con indicación del carácter con que interviene (representante legal, familiar o allegado).

En calidad de ________________ otorgo la autorización para participar en el proyecto de investigación
DENEGACIÓN/REVOCACIÓN DEL CONSENTIMIENTO

Después de ser informado de los fundamentos y objetivos del presente estudio, manifiesto de manera libre mi DENEGACIÓN REVOCACIÓN DE CONSENTIMIENTO para mi participación en el mismo.

En _______________, a ___ de _________________ de ______

Firma investigador

Nombre y apellidos del paciente:

Nº Colegiado

Firma

Denegación/revocación por representación. -El consentimiento podrá ser denegado y/o revocado por su representante legal o persona vinculada por razón familiar o de hecho, en caso de voluntad del/la paciente o incapacidad del paciente, con indicación del carácter con que se interviene (representante legal, familiar o allegado).

En calidad de _________________ deniego/revoco la autorización para participar en el estudio.

Nombre y dos apellidos

DNI

Firma
### Figure 3.

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