

# Does melatonin improve the organ donation process?

|                                        |                                                   |                                                                                                              |
|----------------------------------------|---------------------------------------------------|--------------------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>29/09/2021   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input checked="" type="checkbox"/> Protocol            |
| <b>Registration date</b><br>30/09/2021 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                       |
| <b>Last Edited</b><br>30/05/2022       | <b>Condition category</b><br>Other                | <input type="checkbox"/> Individual participant data<br><input type="checkbox"/> Record updated in last year |

## Plain English summary of protocol

### Background and study aims

Controlled donation after circulatory death (cDCD) and donation after brain death (DBD) have allowed the transplant community to safely increase the organ donor pool. However, it is not without its risky complications, due to cell damage from lack of oxygen to the tissues (hypoxia). Different strategies have been developed to diminish the toxic effects of oxidative stress, but the search for preventive measures and modulation remains a high priority. Melatonin, a molecule that is easy to administer and harmless to the body, has been shown to have antioxidant properties that reduce oxidative stress.

The present work quantifies the oxidative stress and miRNA activation occurring in DCD and DBD donors, and assesses its modulation after melatonin administration.

### Who can participate?

Donors are aged 18 years or above, and suffered from circulatory or brain death

### What does the study involve?

Participants will be randomly allocated to receive melatonin or placebo immediately after death.

### What are the possible benefits and risks of participating?

None

### Where is the study run from?

Virgen del Rocio University Hospital (Spain)

### When is the study starting and how long is it expected to run for?

December 2017 to November 2021

### Who is funding the study?

Fundación Pública Andaluza para la Gestión de la Investigación en Salud de Sevilla (Spain)

### Who is the main contact?

Dr Egea-Guerrero, [jjegeaguerrero@gmail.com](mailto:jjegeaguerrero@gmail.com)

# Contact information

## Type(s)

Scientific

## Contact name

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# Additional identifiers

## Clinical Trials Information System (CTIS)

Nil known

## ClinicalTrials.gov (NCT)

Nil known

## Protocol serial number

AP166562017

# Study information

## Scientific Title

Role of melatonin as a therapeutic strategy against tissue ischemia in the cadaveric donor and its assessment using oxidative stress biomarkers and microRNAs

## Study objectives

The administration of melatonin in the cadaveric donor prior to organ harvesting will alleviate the ischemic damage that occurs from donor extubation to preservation of the graft, and therefore will improve the functionality of the organs after transplantation, and consequently survival of the graft in the recipient. Melatonin will modulate oxidative stress cascades, both at the protein and / or enzyme level (MDA, carbonylated proteins, etc.) and at the miRNA level.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approved 03/12/2018, CEI de los hospitales universitarios Virgen Macarena-Virgen del Rocío (Avda. Manuel Siurot s/n, Seville, Spain; +34 600 16 24 58; administracion.eecc.hvm. sspa@juntadeandalucia.es), ref: 1013-N17

## Study design

Randomized multicenter triple-blind clinical trial

## Primary study design

Interventional

## Study type(s)

Diagnostic

## Health condition(s) or problem(s) studied

The present work quantifies the oxidative stress and miRNAs occurring in controlled donation after circulatory death and donation after brain death, and assesses its modulation after melatonin administration.

## Interventions

Melatonin or placebo was administered via nasogastric tube at the time of determination of death by either neurological or circulatory criteria. The melatonin group received 30 mg of melatonin diluted in 20 ml of sucrose solution (0.4 g/dl). Controls received 20 ml of diluted sucrose solution. Randomization was generated by an electronic system (N-Qery advisor).

## Intervention Type

Drug

## Phase

Phase III

## Drug/device/biological/vaccine name(s)

Melatonin

## Primary outcome(s)

1. Number of valid organs for donation per donor using hospital records
2. Functionality of each organ at 6 and 12 months after transplant following hospital records

## Key secondary outcome(s)

There are no secondary outcome measures

## Completion date

30/11/2021

## Eligibility

### Key inclusion criteria

1. Potential donors after circulatory or brain death
2. Patient suitable for organ donation under Spain's National Transplant Organization protocols
3. Age above 18 years

**Participant type(s)**

Other

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Total final enrolment**

53

**Key exclusion criteria**

1. Potential donors with multiorgan failure
2. Age below 17 years
3. Exclusion criteria for organ donation following Spain's National Transplant Organization protocols

**Date of first enrolment**

15/03/2018

**Date of final enrolment**

15/02/2020

**Locations****Countries of recruitment**

Spain

**Study participating centre**

**Virgen del Rocio University Hospital**

Av. Manuel Siurot s/n.

Seville

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**Study participating centre**

**Virgen de la Victoria University Hospital**

Campus de Teatinos, S/N

Málaga,

Spain  
29010

**Study participating centre**  
**Puerta del Mar University Hospital.**  
Av. Ana de Viya, 21  
Cádiz  
Spain  
11009

**Study participating centre**  
**Virgen de las Nieves University Hospital**  
Av. de las Fuerzas Armadas, 2  
Granada  
Spain  
18014

**Study participating centre**  
**Juan Ramón Jiménez University Hospital.**  
Ronda Norte  
Huelva  
Spain  
21005

## **Sponsor information**

**Organisation**  
Fundación Mutua Madrileña

**ROR**  
<https://ror.org/00skv9577>

## **Funder(s)**

**Funder type**  
Charity

**Funder Name**

Fundación Pública Andaluza para la Gestión de la Investigación en Salud de Sevilla

### Alternative Name(s)

Andalusian Public Foundation for the Management of Health Research in Seville, FISEVI

### Funding Body Type

Government organisation

### Funding Body Subtype

Local government

### Location

Spain

## Results and Publications

### Individual participant data (IPD) sharing plan

All data generated or analysed during this study will be included in the subsequent results publication

### IPD sharing plan summary

Other

### Study outputs

| Output type                             | Details                                                            | Date created | Date added | Peer reviewed? | Patient-facing? |
|-----------------------------------------|--------------------------------------------------------------------|--------------|------------|----------------|-----------------|
| <a href="#">Interim results article</a> |                                                                    | 20/04/2022   | 15/12/2022 | Yes            | No              |
| <a href="#">Other publications</a>      | Using malondialdehyde (MDA) measurement to assess oxidative stress | 20/04/2022   | 20/04/2022 | Yes            | No              |
| <a href="#">Protocol file</a>           | in Spanish                                                         |              | 30/09/2021 | No             | No              |