ISRCTN66157570 https://doi.org/10.1186/ISRCTN66157570

Does melatonin improve the organ donation process?

Submission date
29/09/2021

Recruitment status
No longer recruiting

Registration date
30/09/2021

Overall study status
Completed

Last Edited
30/05/2022

Condition category
Other

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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 Vírgen 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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
No participant information sheet available

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 measure
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

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
22/12/2017

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
50 potential donors

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
Spain
41013

Study participating centre
Virgen de la Victoria University Hospital
Campus de Teatinos, S/N
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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
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Sponsor information

Organisation
Fundación Mutua Madrileña

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Sponsor type
Charity

Website
https://www.fundacionmutua.es/

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

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
30/11/2022

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?
Protocol file	in Spanish		30/09/2021	No	No
Other publications	Using malondialdehyde (MDA) measurement to assess oxidative stress	20/04/2022	20/04/2022	Yes	No
Interim results article		20/04/2022	15/12/2022	Yes	No