# Dose escAlation study of Melatonin in Sepsis: healthy voLunteers

Submission date	Recruitment status  No longer recruiting	[X] Prospectively registered		
29/02/2012		∐ Protocol		
Registration date 24/04/2012	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	Individual participant data		
29/08/2019	Infections and Infestations			

#### Plain English summary of protocol

Background and study aims

Patients who are admitted to an Intensive Care Unit with severe infections (called sepsis) have a very high risk of death. We have shown in laboratory studies that melatonin can be of benefit. This is because melatonin is a very powerful antioxidant and can protect cells and organs against the damage caused by severe infections. We would like to give melatonin to patients with sepsis but we need to get some key information in healthy subjects first so we can decide what dose to give. In this study we will give groups of healthy men different doses of melatonin to provide crucial information for a further study (clinical trial) of melatonin in patients with sepsis. The main aim is to see how well different doses of melatonin are tolerated. We will also measure levels of melatonin and related substances in the blood and urine This will tell us how quickly the doses are processed in the body. If we find that melatonin is able to protect cells in patients with sepsis, this might mean treatment will also reduce the death rate.

#### Who can participate?

Male participants, aged between 18 and 30 years old, weighing less than 100kg, not taking any medication.

#### What does the study involve?

Participants will be given a single dose of melatonin (20-100mg) as oral capsules and will be monitored for 6 hours. This will include heart rate, temperature, blood pressure and also blood sampling and urine collection. A week later participants will fill in a questionnaire. The doses given will gradually increase, with each group of 5 people getting the same dose. The decision to increase the dose will be made by an independent groups of doctors, not the researchers.

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

Melatonin is a naturally occurring hormone which controls the sleep wake cycle. Melatonin manufactured as a drug has been used for several years as a treatment for jet lag. It has also been used in other clinical studies in various doses and the only common side effect is drowsiness. There have been some rare reports of slight nausea with very high doses but other side effects have not been reported. The needle used to put a tube into a vein to take blood

samples may sting a bit and may cause bruising but this is likely to be very transient. There is no direct benefit to taking part but the study will provide essential information which will help decide what dose of melatonin to give to patients in the future.

Where is the study run from?

At Aberdeen Royal Infirmary in Scotland and is organised by researchers at the University of Aberdeen (UK)

When is the study starting and how long is it expected to run for? June 2012 and will last for 1 year

Who is funding the study? Chief Scientist Office (Experimental and Translational Medicine Board), UK

Who is the main contact? Professor Helen Galley h.f.galley@abdn.ac.uk

# Contact information

## Type(s)

Scientific

#### Contact name

Prof Nigel R Webster

#### Contact details

University of Aberdeen Institute of Medical Sciences Aberdeen United Kingdom AB25 2ZD

# Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number NCT01724424

**Secondary identifying numbers** 3/057/11

# Study information

#### Scientific Title

A dose escalation study of melatonin in healthy volunteers as a potential treatment for sepsis

#### Acronym

DAMSEL1

#### **Study objectives**

The aim of this proposed study is to administer melatonin to healthy volunteers to determine the tolerability at each dose and pharmacokinetics of melatonin using a standard dose escalation study design. We will measure the concentrations of melatonin and its major metabolites to determine a dosing interval and clearance.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Not provided at time of registration

#### Study design

Single-centre phase I open-label dose-escalation study

## Primary study design

Interventional

#### Secondary study design

Non randomised study

#### Study setting(s)

Hospital

# Study type(s)

Treatment

#### Participant information sheet

Not available in web format, please contact damsel.study@gmail.com to request a patient information sheet

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

Sepsis

#### **Interventions**

Oral melatonin, 20-100mg, single dose in cohorts of 5 subjects

#### Intervention Type

Other

#### Phase

Phase I

#### Primary outcome measure

Tolerance of the oral melatonin dose with no adverse events and approval by the Data Monitoring Committee to proceed to the next dose

#### Secondary outcome measures

Plasma levels and clearance of melatonin/metabolites at different doses measured at intervals up to 6 hours

# Overall study start date

01/06/2012

# Completion date

14/06/2013

# Eligibility

## Key inclusion criteria

- 1. Male
- 2. Aged 18-30 years
- 3. <100kg
- 4. Not taking medication

# Participant type(s)

**Patient** 

#### Age group

Adult

#### Lower age limit

18 Years

#### Upper age limit

30 Years

#### Sex

Male

# Target number of participants

20

#### Key exclusion criteria

- 1. Female
- 2. <18 or >30 years
- 3. >100kg
- 4. Taking regular medication

#### Date of first enrolment

01/06/2012

#### Date of final enrolment

14/06/2013

# Locations

#### Countries of recruitment

Scotland

**United Kingdom** 

# Study participating centre Aberdeen Royal Infirmary

Intensive Care Unit Aberdeen United Kingdom AB25 2ZN

# Sponsor information

#### Organisation

University of Aberdeen (UK)

# Sponsor details

Polwarth Building Foresterhill Aberdeen Scotland United Kingdom AB25 2ZD

#### Sponsor type

University/education

#### Website

http://www.abdn.ac.uk/

#### ROR

https://ror.org/016476m91

# Funder(s)

# Funder type

Government

#### **Funder Name**

Chief Scientist Office (UK) ref: ETM/167

# Alternative Name(s)

CSO

# **Funding Body Type**

Government organisation

# **Funding Body Subtype**

Local government

#### Location

United Kingdom

# **Results and Publications**

# Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

# IPD sharing plan summary

Not expected to be made available

#### **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2014		Yes	No