Ketanserin effects on Peripheral Temperature and Lactate

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To determine the effects of a continuous ketanserin infusion on peripheral temperature and lactate clearance in critically ill patients with either a high lactate or a high deltaT.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON46490

Source
ToetsingOnline

Brief title
KoPTaL

Condition

- Other condition

Synonym
Microcirculatory failure

Health condition

circulatie stoornissen bij intensive care patiënten

Research involving
Human

Sponsors and support

Primary sponsor: Onze Lieve Vrouwe Gasthuis
Source(s) of monetary or material Support: eigen middelen van de betreffende ICU's

Intervention

Keyword: Intensive Care, Ketanserin, Lactate, Microcirculation

Outcome measures

Primary outcome

Change in DeltaT (measured per hour)

Secondary outcome

Change in lactate (measured per 2 hours)

Lactate clearance is calculated as described in chapter 2 of the protocol.

To calculate lactate clearance every two hours a 2 ml arterial blood sample for

lactate measurement will be collected (at T=0, T=2hr, T=4 hr, T=6 hr and T=8hr)

and sent for immediate analysis.

In addition, at T=4 hr and T=8 hr a 6 ml blood sample will be drawn to

determine ketanserin serum levels in retrospect.

Study description

Background summary

Rationale:
A high blood lactate and a high peripheral to central temperature difference (deltaT) are associated with a higher mortality in critically ill patients [Lima 2009, Bourcier 2016, Jansen 2010]. Both measures are signs of a reduced microcirculatory bloodflow or vasoconstriction and are associated with shock [Joly 1969,Lima 2009]. On the other hand, it has not been shown yet that interventions leading to improvement of this temperature gap reduces mortality or improves any other outcome measurement. Moreover, it is unknown which medication can best be used to improve deltaT and lactate clearance.
Ketanserin is being used in the intensive care setting for decades to optimize circulatory parameters. Ketanserin is a serotonin type 2-receptor blocker (5-HT2). Blocking the 5-HT2 receptor with ketanserin can attenuate pathological

vasoconstriction. In these ways ketanserin can reduce vasoconstriction and can improve the microcirculation. As a consequence, the enhanced blood flow in the skin will increase the peripheral temperature and decrease deltaT. At the same time an increased flow in the microcirculation may lead to a reduction in lactate production

Study objective

To determine the effects of a continuous ketanserin infusion on peripheral temperature and lactate clearance in critically ill patients with either a high lactate or a high deltaT.

Study design

A multicentre double blind randomized controlled trial.

Intervention

The intervention is a continuous pump driven Ketanserin infusion of 0.75 ug/kg/min for eight hours.

The control group will receive the same volume of glucose 5%.

Study burden and risks

The risks of ketanserin infusion are limited but can be a QTc prolongation and a slight decrease in blood pressure. However, these effects seldomly occur [Hoogstraaten 2014; van der Voort2017].

The study needs an arterial blood sample on inclusion, and after 2, 4, 6 and 8 hours of 1.5 ml each. In addition, a 6 ml blood sample at T=4 and T=8 hours.*

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- DeltaTemperature greater than 6.0 °C.
- Age 18 years or older
- Admitted to the ICU for any reason
- Signed informed consent from the patient or legal representative

Exclusion criteria

- Pregnancy
- No possibility to obtain informed consent
- QTc above 550 msec,
- Arrhythmias, including bradycardia defined as a heart rate below 50/min; 2nd and 3rd degree AV block; ventricular tachycardia
- Blood Potassium level < 3.5 mmol/l
- Blood Magnesium level <0.5 mmol/l
- Allergy for ketanserin
- DeltaTemperature less than 6°C.
- Patients undergoing therapeutic hypothermia
- Patients admitted after cardiac arrest
- Patients admitted after cardiac surgery

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-04-2018
Enrollment:	120
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Ketensin
Generic name:	Ketanserin
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	24-10-2017
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	02-03-2018
Application type:	First submission

Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2017-003362-27-NL
CCMO	NL62916.100.17