Levosimendan in Acute Kidney Injury Study

Published: 18-03-2014
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The objective of this study is to investigate whether Levosimendan is able to lower creatinine levels as a measure of kidney failure and if urinary output can be increased.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Renal disorders (excl nephropathies)
Study type	Interventional

Summary

ID

NL-OMON43813

Source
ToetsingOnline

Brief title
LAKIS

Condition

- Renal disorders (excl nephropathies)

Synonym
Acute kidney injury, kidney failure

Research involving
Human

Sponsors and support

Primary sponsor: Viecuri Medisch Centrum voor Noord-Limburg
Source(s) of monetary or material Support: Orion Pharma, Orion Corporatie, Finland,VieCuri Medisch Centrum onderzoeksfonds en een onderzoeksgrant van de firma Orion Pharma

Intervention

Keyword: AKI, Intensive Care, Levosimendan, RIFLE

Outcome measures

Primary outcome

To evaluate in ICU patients with AKI defined by an increase of NGAL whether

Levosimendan can improve kidney function by an improved eCC of 10 ml per minute

within 72 hours.

Secondary outcome

Improvement of renal oxygenation

Improvement of eGFR and urine output

Evaluate Cardiac Output

Evaluation of Cardiac Biomarkers

Evaluate indication for renal replacement therapy

To assess mortality on day 28

Study description

Background summary

The aim of the study is to evaluate if Levosimendan in adult ICU patients with AKI can improve kidney function

Study objective

The objective of this study is to investigate whether Levosimendan is able to lower creatinine levels as a measure of kidney failure and if urinary output can be increased.

Study design

This trial is set up as a pilot for a larger randomized intervention trial

including 68 patients, randomized into two cohorts. The experimental group receives standard treatment supplemented by levosimendan for 24 hours following onset of AKI and control group is to receive standard care as defined by our local care protocols, combined with a placebo for levosimendan.

Intervention

Levosimendan infusion versus placebo infusion

Study burden and risks

The risk for participating patients in the investigation is limited. This trial is building on foreign research done with levosimendan which has been demonstrated to be beneficial in many patient groups, including patients with renal problems. Biomarker measurements currently find good use in Dutch intensive care units, and should be considered routine practice within the ICU setting. In the opinion of the investigators, this trial is considered a low risk for patients. In the opinion of the investigators the burden of this trial is limited but the potential benefits could be quite large as improved renal function has been demonstrated to be indicative of a more preferable outcome.

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

*Over age of 18
*Informed consent is received
*Admitted to ICU
*Receiving diagnosis AKI with RIFLE criteria risk score *Injury (I) ***
(***For diagnosis of AKI, an previous serum creatinine value has to be available in the electronic patient record. However, creatinine is known for its fluctuations, mainly in critically ill patients. Therefore, for diagnosis of AKI, the serum creatinine at moment of possible inclusion in our trial will be compared to a previous value which is a maximum of 14 days old)

Exclusion criteria

*Failure to obtain written consent to participate from patient or legal representative (by deferred consent)
*Patients entering the ICU for post-operative observation with an estimated length of stay less than 24 hrs
*Moribund patients
*Patients under the age of 18
*Pregnancy
*Patients with mono kidney or just one functional kidney (i.e: contracted kidneys)
*Patients with post renal obstruction of any cause
*Renal replacement therapy initiated before admission due to Chronic Kidney Disease or predialysis
*Hypersensitity to levosimendan experienced by previous treatments
*Severe hypotension (MAP<60mmHg) and/or tachycardia (>180bpm) despite measures
*Significant pre-existing mechanical obstruction affecting ventricular filling or outflow or both (*** Mechanical obstruction is defined as an *mild* or * moderate* in severity, as judged by the cardiologist performing previous echocardiogram)
*Severe hepatic impairment (ALAT/ASAT>400U/L)
*Patients will be excluded if the treating physician judges that study participation is undesirable due to an assumed short life expectancy
*Known history of Torsades de Pointes

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	68
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Simdax
Generic name:	Levosimendan

Ethics review

Approved WMO Date:	18-03-2014
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	19-12-2014
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	EUCTR2012-004979-39-NL
ClinicalTrials.gov	NCT01720030
CCMO	NL42546.068.14