

# The effect of two different heart-lung machines, Twin-Pulse Life Support and standard used heart-lung machine, on the systemic inflammation and pattern of microvascular blood flow. A prospective randomised clinical trial.

Published: 08-08-2007

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Analysis of the effects of the Twin-Pulse Life Support on on the systemic inflammatory response and the effect on microvascular blood flow in ocmparison to standard used Extracorporeal Circuit Device

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Myocardial disorders
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON30555

### Source

ToetsingOnline

### Brief title

The effect of TPLS compared to standard HLM

### Condition

- Myocardial disorders
- Cardiac therapeutic procedures

### Synonym

coronary artery atherosclerosis

## Research involving

Human

## Sponsors and support

**Primary sponsor:** Academisch Ziekenhuis Maastricht

**Source(s) of monetary or material Support:** Ministerie van OC&W, NewheartBio, Seoul, Korea, NewheartBio; Seoul; Korea

## Intervention

**Keyword:** microvascular blood flow, systemic inflammation, T-PLS

## Outcome measures

### Primary outcome

Systemic inflammatory response

### Secondary outcome

Analyses of the effect of Twin-PulseLifeSupport on microvascular blood flow

## Study description

### Background summary

the Twin-Pulse Life support is an extracorporeal circulation which uses a pulsating mechanism, which is suggested to have positive effect on the systemic inflammatory response and which could lead to a better microvascular blood flow.

T-PLS could be an emergency treatment in case of severe cardiac or pulmonary failure.

### Study objective

Analysis of the effects of the Twin-Pulse Life Support on the systemic inflammatory response and the effect on microvascular blood flow in comparison to standard used Extracorporeal Circuit Device

### Study design

Randomized prospective clinical trial

## Study burden and risks

no additional risks compared to the standard used heart-lung machine, such as pump stop or oxygenator failure.

## Contacts

### Public

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6229 HX Maastricht  
Nederland

### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

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

### Inclusion criteria

primary CABG  
age: 55 - 75 years  
left ventricular ejection fraction > 45%

## Exclusion criteria

renal dialysis  
history of stroke  
pulmonary insufficiency

## Study design

### Design

Study phase:	3
Study type:	Observational invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2006
Enrollment:	20
Type:	Anticipated

### Medical products/devices used

Generic name:	Twin-Pulse Life Support
Registration:	No

## Ethics review

Approved WMO	
Date:	08-08-2007
Application type:	First submission

Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO	
Date:	29-10-2007
Application type:	Amendment
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
CCMO	NL14737.068.06