

# A prospective, nonrandomized, noninterventional study to compare Nexfin CO-trek cardiac output with thermodilution cardiac output

<b>Submission date</b> 03/07/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 10/09/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 12/05/2021	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Cardiac output is the amount of blood the heart pumps into the circulation per minute. In patients scheduled for cardiac (heart) surgery, cardiac output is measured using a catheter (tube) in the pulmonary artery. This is an invasive method. This study aims to compare the invasive method with a completely non-invasive method of cardiac output measurement. The non-invasive method uses a single air-inflatable cuff around one of the fingers. The non-invasive measurement has no potential harmful side effects.

### Who can participate?

Patients aged over 18 scheduled for cardiac surgery.

### What does the study involve?

The cuff will be applied directly before the operation starts, but before you are being anesthetized. We compare the new method against the standard method of measuring cardiac output during operations. The standard method involves placement of a special central venous line. In patients undergoing cardiac surgery, the latter method is used as the standard of care. Therefore the only procedure the this study involves is the extra measurement using the finger cuff.

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

Participation in this study has no potential benefits for you as a patient. Because the new method is completely noninvasive, participation to this study has very little associated risks. The only adverse effect of the finger cuff is a temporarily bluecoloring of the fingertip. This is completely harmless and the color of the finger immediately normalizes when the cuff is removed.

Where is the study run from?

Academic Medical Center (Netherlands), VU Medical Center (Netherlands), Cooper University Hospital (USA).

When is the study starting and how long is it expected to run for?

November 2013 to February 2015.

Who is funding the study?

Edwards Lifesciences (USA).

Who is the main contact?

Dr Niek Sperna Weiland

## Contact information

### Type(s)

Scientific

### Contact name

Dr Niek Sperna Weiland

### Contact details

Meibergdreef 9  
Amsterdam-Zuidoost  
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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

### Secondary identifying numbers

Protocol Revision C/ METC 2013\_068 / NL44270.018.13

## Study information

### Scientific Title

A prospective, nonrandomized, noninterventional study to compare Nexfin CO-trek cardiac output with thermodilution cardiac output

### Study objectives

The primary objective of this study is to show the accuracy of Cardiac Output measurement with the ccNexfin by assessment of agreement between ccNexfin and Cardiac Output measurement by pulmonary thermodilution using a Pulmonary Artery Catheter. To demonstrate this, the difference between the two methods must be smaller than the minimum difference considered as clinically significant (within 0.6 liters per minute difference).

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Medisch Ethische Toetsingscommissie Academisch Medisch Centrum, internal reference number METC 2013\_068

**Study design**

Observational multicenter study

**Primary study design**

Observational

**Secondary study design**

Prospective nonrandomized noninterventional

**Study setting(s)**

Hospital

**Study type(s)**

Diagnostic

**Participant information sheet**

Not available in web format. Please contact the details below to request a patient information sheet

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

Cardiac output measurement

**Interventions****PRIOR TO PROCEDURE**

The standard preevaluation will include:

1. Informed consent
2. Screening for inclusion and exclusion criteria
3. Basic medical history.
4. Baseline information, findings, and results will be entered in the eCRFs from the source documents including:
  - 4.1. General Information (subject ID number, date & time of consent, age/gender/height/weight)
  - 4.2. Clinical Information (ASA class, relevant medical history, use of medication, cardiac rhythm, reason for surgery)

For subjects who are enrolled in the study (signed an informed consent) but who do not undergo the required measurements, the eCRFs will not be completed. The site must retain the subject's informed consent. Verification that the subject signed the consent will occur during an onsite monitoring visit.

**DURING PROCEDURE**

The CO comparison will be made in the period before the extracorporeal circulation and preferably in baseline as well as in Trendelenburg/reverse Trendelenburg position as clinically required. The following items will be performed:

1. The measurements are performed in the OR during anesthesia

2. ccNexfin cuff application to the appropriate finger of the arm with the arterial line
3. Start of ccNexfin measurement
4. The Investigator will perform intermittent TD measurements as required. Preloading status (baseline, [reverse] Trendelenburg) will be noted.
5. Marking of this period on the ccNexfin recording in order to be able to pair TD measurements with beats recorded with the ccNexfin. Pairing of the cardiac cycles for the analyses is described in Appendix 6.
6. General Information (subject ID number, time of surgery start, study/reference device information and measurement sites)
7. Clinical Information as available (fluid administration, fluid loss, fluid balance, vasoactive /inotropic medications administered, mechanical ventilation settings [tidal volume, PEEP & FiO2]; all with time instants).

## POSTPROCEDURE

Study is complete when cardiopulmonary bypass is initiated or when the heart or vascular system is physically manipulated. Devices will be removed from the patients at the end of the surgical procedure

## Intervention Type

Device

## Primary outcome measure

The primary study endpoint is the acquisition of the cardiac output values of the two devices to meet an acceptance criterion of Bias < 0.6 liters per minute.

## Secondary outcome measures

The secondary study endpoints (and acceptance criteria) are:

1. The comparability of both methods as determined by Bland-Altman analysis (Bias < 0.6, Percentage Error < 40.4)
2. The precision of Nexfin CO-trek versus TD (no acceptance criterion)
3. The Pearson correlation coefficient of the CO pairs of the two methods (no acceptance criterion)

## Overall study start date

26/11/2013

## Completion date

12/02/2015

# Eligibility

## Key inclusion criteria

1. Subjects must be at least 18 years of age
2. Subjects must give signed written informed consent
3. Subjects' height and weight must be accurately obtained prior to study start

## Participant type(s)

Patient

## Age group

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

Maximally 60

**Total final enrolment**

55

**Key exclusion criteria**

1. Aortic or tricuspid valve regurgitation
2. Aortic stenosis or aneurysms
3. History of uncontrolled cardiac arrhythmia
4. Any peripheral vascular disease or conditions such as Raynaud's disease or Buerger's disease
5. Insufficient perfusion of the digits
6. Inability to place the finger cuff appropriately due to subject anatomy or condition
7. Known pregnancy
8. Patients being treated with an intra-aortic balloon pump
9. Patient is currently participating in an investigational drug or another device study that clinically interferes with the study endpoints

**Date of first enrolment**

11/12/2013

**Date of final enrolment**

14/12/2014

## **Locations**

**Countries of recruitment**

Netherlands

United States of America

**Study participating centre**

**Academic Medical Center**

Meibergdreef 9

Amsterdam

Netherlands

1105 AZ

**Study participating centre**

**VU Medical Center**  
De Boelelaan 1117  
Amsterdam  
Netherlands  
1081 HV

**Study participating centre**  
**Cooper University Hospital**  
1 Cooper Plaza  
Camden, NJ  
United States of America  
08103

## **Sponsor information**

**Organisation**  
Edwards Lifesciences LLC

**Sponsor details**  
One Edwards Way  
Irvine, CA  
United States of America  
92614 USA

**Sponsor type**  
Industry

**ROR**  
<https://ror.org/04jhyte11>

## **Funder(s)**

**Funder type**  
Industry

**Funder Name**  
Edwards Lifesciences

**Alternative Name(s)**  
Edwards, Edwards Lifesciences Corporation, Edwards Lifesciences Corp., Edwards Lifesciences LLC, ELC

**Funding Body Type**

Government organisation

**Funding Body Subtype**

For-profit companies (industry)

**Location**

United States of America

## Results and Publications

**Publication and dissemination plan**

To be confirmed at a later date

**Intention to publish date**

30/03/2016

**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Available on request

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		01/04/2018	12/05/2021	Yes	No