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

Submission date
03/07/2015

Recruitment status
No longer recruiting

Registration date
10/09/2015

Overall study status
Completed

Last Edited
12/05/2021

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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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?
Results article		01/04/2018	12/05/2021	Yes	No