Clinical evaluation of the Carmat total artificial heart for patients with advanced heart failure

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Ethical review	Approved WMO
Status	Suspended
Health condition type	Heart failures
Study type	Interventional

Summary

ID

NL-OMON55007

Source
ToetsingOnline

Brief title
Evaluation of the Carmat total artificial heart

Condition

- Heart failures
- Cardiac therapeutic procedures

Synonym
end stage Heart failure

Research involving
Human

Sponsors and support

Primary sponsor: CARMAT SA
Source(s) of monetary or material Support: medical device industry

Intervention

Keyword: biventricular support, Heart failure, total artificial heart

Outcome measures

Primary outcome

Survival at 180 days after Carmat TAH implantation.

Secondary outcome

- Overall survival

- Health status change as measured by EuroQol, EQ-5D-5L and SF36

- Functional status change as measured by NYHA and 6MWT

- Adverse events incidence and frequency

- Time to first discharge and incidence of re-hospitalization

Study description

Background summary

For the most severe forms of cardiac dysfunction, which lead to irreversible biventricular failure, cardiac transplantation remains the only effective therapy. There is a significant shortfall in the availability of human donor hearts. Mechanical circulatory support (MCS) devices considered for patients with advanced HF include VADs and TAHs. The type of device used depends on the stage of HF and whether one or both ventricles are affected. Currently, the SynCardia device is the only approved TAH on the market. This first generation of Total Artificial Hearts (TAH) are pneumatically-driven and have been used as a bridge to transplantation, at the cost of high morbidities related to the devices. Carmat has developed a biocompatible, biventricular mechanical heart that is designed to replicate the functionality and morphology of the human heart as closely as possible using self-regulatory mechanisms and biocompatible materials.

Study objective

The primary objective of the study is survival on a Carmat device at 180 days post-implant* or survival to cardiac transplantation if occurring before 180

days post-implant**. * The beginning of the implant procedure is defined as the start of the sternotomy. ** A patient will be considered to have survived to heart transplant when anesthetic induction for heart transplant has started. The purpose of this clinical study is to demonstrate safety and performance of the Carmat TAH in patients with advanced heart failure.

Study design

This is a prospective, international multi-center, interventional, single-arm study. After a screening process, subjects will be enrolled in the clinical study if they meet clinical and anatomic criteria. In case of screening failure, subjects will be followed in an observational phase for outcomes data (e.g. survival, therapeutic option). Patients will be evaluated at 6 months (180 days) for primary and secondary endpoints with further follow-up assessments up to 2 years.

Intervention

Screening, baseline, implant and hospitalization period until discharge, evaluation visit at 1M, 2M, 3M, 4M, 5M, 6M, 9M, 12M, 18M en M24 post-implantation.

Study burden and risks

The Carmat Total Artificial Heart (TAH) is an integrated electro-hydraulically-driven system intended for full cardiac support in patients suffering from advanced heart failure. The key features of the device are the following: 1. First auto-regulated, sensorbased functioning TAH 2. Designed for optimized haemocompatibility 3. Designed for patient comfort and mobility. The Carmat TAH is intended for patients suffering from irreversible bi-ventricular heart failure, either transplant-eligible (mid-term duration support) or non-eligible (long-term/definitive support). It is designed for in-hospital and out-of-hospital use.

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

1) Patient age: 18 to 75 years
2) Inotrope dependent or cardiac Index (CI) < 2.2 L/min/m2 if inotropes are contraindicated (heart failure due to restrictive or constrictive physiology).
3) On Optimal Medical Management as judged by the investigator based on current Heart Failure practice guidelines (ESC/AHA)
4) Eligible to biventricular Mechanical Circulatory Support according to ISHLT guidelines for mechanical circulatory support:
a. Biventricular failure with at least two of the following hemodynamic/ echocardiographic measurements implying right heart failure:
1). RVEF <= 30%
2. RVSWI <= 0.25 mmHg*L/m2
3. TAPSE <= 14mm
4. RV-to-LV end-diastolic diameter ratio > 0.72
5. CVP > 15 mmHg
6. CVP-to-PCWP ratio > 0.63
7. Tricuspid insufficiency grade 4
b. Treatment-refractory recurrent and sustained ventricular tachycardia or ventricular fibrillation in the presence of untreatable arrhythmogenic pathologic substrate
c. Heart failure due to restrictive or constrictive physiology (e.g., hypertrophic cardiomyopathy, cardiac amyloidosis / senile or other infiltrative heart disease)
5) Anatomic compatibility confirmed using 3D imaging (CT-scan)
6) Patient*s affiliation to health care insurance, if local requirement

7) Patient has signed the informed consent and committed to follow up study requirements

Exclusion criteria

1) Body Mass Index (BMI) < 15 or > 47
2) Existence of any ongoing non-temporary mechanical circulatory support
3) Existence of any temporary mechanical circulatory support other than IABP or Impella
4) History of cardiac or other organ transplant
5) Patients who have required cardiopulmonary resuscitation for > 30 minutes within 14 days prior to implant
6) Known intolerance to anticoagulant or antiplatelet therapies
7) Coagulopathy defined by platelets < 100k/µl or INR >= 1.5 not due to anticoagulant therapy
8) Cerebro-vascular accident < 3 months or symptomatic or a known > 80% carotid stenosis
9) Known abdominal or thoracic aortic aneurysm > 5 cm
10) Severe End-organ dysfunction as per any of the following criteria:
a. Total bilirubin > 100 µmol/L (5,8 mg/dl) or cirrhosis evidenced by ultrasound, CT-scan and positive biopsy
b. GFR < 30ml/min/1.73m2
11) History of severe Chronic Obstructive Pulmonary Disease or severe restrictive lung disease
12) Recent blood stream infection (<7 days)
13) Documented amyloid light-chain (AL amyloidosis)
14) Hemodynamically significant peripheral vascular disease accompanied by rest pain or extremity ulceration
15) Illness, other than heart disease, that would limit survival to less than 1 year
16) Irreversible cognitive dysfunction, psychosocial issues or psychiatric disease, likely to impair compliance with the study protocol and TAH management
17) Participation in any other clinical investigation that is likely to confound study results or affect the study
18) Pregnancy or breast feeding (women of childbearing age will have to show negative pregnancy test)

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	06-09-2021
Enrollment:	3
Type:	Actual

Medical products/devices used

Generic name:	Active Implantable Medical Device: CARMAT Total Artificial Heart (TAH)
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO Date:	03-06-2021
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	02-05-2024
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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
ClinicalTrials.gov	NCT02962973
CCMO	NL74452.041.20