kofam

Koordinationsstelle Forschung am Menschen

CASE STUDY

A single arm, multi-centre clinical trial to evaluate the HeartWare® ventricular assist system (VAS) for destination therapy of advanced heart failure

CATEGORISING

Kind
Research project involving living people

Type

Subtype
Clinical trial with medical devices (according to ClinO-MD)

BACKGROUND

Routine treatment with left ventricular assist devices (LVADs) bridges transplantation for patients with advanced heart failure. We aim to determine the safety and effectiveness of the HeartWare® Ventricular Assist System in patients with chronic advanced stage left ventricular ineligible for cardiac transplantation. The HeartWare® Ventricular Assist System is marketed in several countries, but the use of the System in Switzerland has been prohibited by Swissmedic.

METHODS

We include patients with advanced heart failure symptoms (Stage D/NYHA Class IIIB or IV, ≥18 years old) who have received and failed optimal medical therapy, and are ineligible for cardiac transplantation. All patients receive the HeartWare® Ventricular Assist System. The primary endpoint of the trial is survival and freedom of re-interventions until cardiac transplantation.

SOURCE

http://clinicaltrials.gov/ct2/show/record/NCT01166347?term=HeartWare+Ventricular+Assist+System&rank=1

QUESTIONS OF THE CATEGORISER

Does the research project come under the scope of application of the Human Research Act?
Yes

BECAUSE
This project was based on a study protocol that defined the exact procedures that should be used. A relatively large number of persons were included, and outcomes were not based on individual cases ("method-driven search for generalizable knowledge", defined as research by HRA). Adults ("persons") who suffered from advanced heart failure symptoms (Class IIIB or IV) were eligible ("research concerning human diseases").

Is the research project a project involving living persons?
Yes

BECAUSE
Adults ("persons") who suffered from advanced heart failure symptoms (Class IIIB or IV) were included in this study.

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Is the research project a clinical trial as defined by ClinO or ClinO-MD?
Yes

BECAUSE
According to the study protocol, the investigators treated adults with advanced heart failure symptoms (Class IIIB or IV) with the HeartWare® Ventricular Assist System ("health-related intervention [therapeutic measure]"). These adults were "prospectively assigned" to the intervention, and the study estimated the proportion of stroke-free survival participants at two years ("to investigate its effects on health or on the structure and function of the human body").

Does the trial involve investigating medicinal products (including combinations according to Art. 2 Para. 1 Letters f and g Medical Device Ordinance (MedDO) from the July 1, 2020)?
No

BECAUSE

Does the trial involve investigating a medical device (in vitro diagnostics excluded) or any other device as defined in Article 1 of the Medical Devices Ordinance (MedDO) (Status as of 26 May 2022)?
Yes

BECAUSE
This clinical trial investigated the effects of HeartWare® Ventricular Assist System ("medical device").

Does the trial investigate an intervention that is neither a therapeutic product nor a transplant product, nor a product according to Art. 2a para. 2 Therapeutic Products Act (TPA) (Status from May 26, 2021), nor a transplant?
No

BECAUSE

Does the trial investigate gene therapy or a pathogenic organism?
No

BECAUSE

Does the medical device bear a conformity mark?
Yes

BECAUSE
This trial investigated the effects of the HeartWare® Ventricular Assist System ("medical device"). The device passed the required conformity assessment procedure and bears a CE mark.

In Switzerland, is it forbidden to make the medical device available on the market, to put it into service or to use it on a person?
Yes

BECAUSE
This trial investigated the effects of the HeartWare® Ventricular Assist System ("medical device"). The device passed the required conformity assessment procedure and bears a CE mark. However, use of the HeartWare® Ventricular Assist System was prohibited in Switzerland during conduct of the trial.

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