FRAILTY Classification Algorithm for the Corsano CARDIOWATCH 287-2: a Development and Validation Study

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Ethical review	Approved WMO
Status	Pending
Health condition type	Heart failures
Study type	Observational non invasive

Summary

ID

NL-OMON57331

Source ToetsingOnline

Brief title FRAILTY-CARDIOWATCH study

Condition

• Heart failures

Synonym Frailty; impairment; brittleness

Research involving Human

Sponsors and support

Primary sponsor: Corsano Health B.V. **Source(s) of monetary or material Support:** Corsano Health B.V.

Intervention

Keyword: frailty, remote patient monitoring, wristband

Outcome measures

Primary outcome

Frailty algorithm of Corsano Cardiowatch epoch agreement with corresponding G8

measured in overall accuracy and weighted kappa between Frailty algorithm of

Corsano Cardiowatch and the golden standard G8 questionnaire (frail or

non-frail) and the FRAIL score (frail, pre-frail and non-frail).

Secondary outcome

Frailty algorithm of Corsano Cardiowatch epoch agreement with 6MWT measured in

overall accuracy, sensitivity and specificity.

Study description

Background summary

Wrist wearables have the potential to continuously and accurately classify frailty. The Corsano CardioWatch 287-2 is such a medical device with that potential. The collection of clinical data in phase I of this study is required to develop and train a frailty algorithm for the Corsano CardioWatch 287-2.

Study objective

The main objective of phase I of this study is to collect data which will be used to develop and train a frailty classification algorithm.

Primary objective: The main objective is to determine the agreement of the frailty classification between the Corsano CardioWatch and the gold standard Geriatric 8 (G8) questionnaire, and the FRAIL scale. Secondary objective: To determine the accuracy of frailty classification between the Corsano CardioWatch and the 6-minute walk test (6MWT). In addition, the 6MWT data will be used to further validate the Corsano gait algorithm.

Study design

These patients will be asked to undergo a G8 assessment, FRAIL scale assessment, 6MWT and wear the Corsano CardioWatch 287-2 for 6 days, 3 days approximately 2 weeks before the procedure and 3 days approximately 2 months after the procedure. In the first set of patients (n=20) this data will be used to train a classification algorithm for the Corsano CardioWatch 287-2 (stage I). In a second set of patients (n=20), this data will be used to validate the new classification algorithm of the Corsano CardioWatch 287-2 (stage II). The current protocol focuses only on phase I. Later on, phase II will be researched.

Study burden and risks

The study involves conducting two G8 questionnaires, two FRAIL scale assessments, two 6MWT and wearing the Corsano CardioWatch 287-2 for 6 days in total. Therefore, the study burden and risks are minimal. However, after development of the Corsano CardioWatch 287-2 frailty classification algorithm, the device has the potential to allow continuous and remote frailty monitoring.

Contacts

Public Corsano Health B.V.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Elderly (65 years and older)

Inclusion criteria

- * >= 70 years old
- * Able to provide consent
- * Be scheduled to undergo on of the following procedures:
- ** Aortic valve replacement
- ** Mitral valve repair with MitraClip
- ** Implantation of a pacemaker
- ** Percutaneous coronary intervention (PCI)

Exclusion criteria

* Unable to wear the Corsano CardioWatch 287-2 due to reasons such as allergic reactions, wounds, amputations etc.;

- * Unable or unwilling to sign informed consent;
- * Significant mental or cognitive impairment;
- * Cardiovascular disease where heart rate is not measurable (e.g. LVAD)

Study design

Design

Study type: Observational non invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Diagnostic	

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-12-2024
Enrollment:	40

4 - FRAILTY Classification Algorithm for the Corsano CARDIOWATCH 287-2: a Developmen ... 13-05-2025

Type:

Anticipated

Medical products/devices used

Generic name:	Corsano CardioWatch 287-2
Registration:	Yes - CE intended use

Ethics review

Approved WMO	
Date:	07-03-2025
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

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 CCMO **ID** NL86687.058.24