Blood Pressure Treatment by the Corsano CardioWatch 287-2 Evaluation Study

Published: 18-04-2024
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To assess the ability to track blood pressure decrease measured by the Corsano CardioWatch 287-2 after a period of 28 days of antihypertensive drug treatment initiation, uptitration or change in antihypertensive drugs.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Vascular hypertensive disorders
Study type	Observational non invasive

Summary

ID

NL-OMON56722

Source
ToetsingOnline

Brief title
BPTreat Study

Condition

- Vascular hypertensive disorders

Synonym
high blood pressure, hypertension

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: blood pressure, drug treatment change, remote patient monitoring, wristband

Outcome measures

Primary outcome

Absolute decrease and standard deviation of SBP and DBP after change of treatment measured by the Corsano Cardiowatch 287-2 after 28 days, compared to blood pressure measured by an automatic blood pressure cuff.

Secondary outcome

(1) Mean bias and limits of agreement between blood pressure measured by the Corsano CardioWatch 287-2 and blood pressure measured by an automatic blood pressure cuff.

(2) Pearson correlation coefficient between blood pressure decrease measured by the Corsano CardioWatch 287-2 and blood pressure decrease measured by an automatic blood pressure cuff.

Study description

Background summary

Wearables have the potential to monitor patients remotely. The Corsano CardioWatch 287-2 is such a medical device that can monitor long-term blood pressure. The device has been validated using clinical trials in hospitals, but evaluation in the intended remote setting during treatment is lacking.

Study objective

To assess the ability to track blood pressure decrease measured by the Corsano CardioWatch 287-2 after a period of 28 days of antihypertensive drug treatment initiation, uptitration or change in antihypertensive drugs.

Study design

Observational study in which blood pressure will be measured by the investigative device and a reference device at pre-treatment and after 28 days. The investigative device is the Corsano CardioWatch 287-2, which measures blood pressure through optical photoplethysmography (PPG). The reference method involves an automatic blood pressure cuff.

Study burden and risks

The study involves wearing of the Corsano CardioWatch 287-2 for 28 days and blood pressure measurements at the beginning and ending of this period, which does not impose a significant risk to the patient but does call on the patient's time for a longer period of time. The study is necessary for the evaluation of the Corsano CardioWatch 287-2 in its intended remote care setting. The device has the potential to improve the monitoring of blood pressure during antihypertensive drug treatment initiation, uptitration or change in antihypertensive drugs, which can provide doctors with more insight into a patient's hemodynamics. This potential can only be realized by conducting the study and having patients wear the wristband at home for an extended period of time during a change in antihypertensive treatment.

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

* aged between 18 and 80 years old;
* able to provide consent;
* has uncontrolled blood pressure and medical indication for antihypertensive drug treatment initiation, uptitration or change in antihypertensive drugs.

Exclusion criteria

* unable to wear the Corsano CardioWatch 287 due to reasons such as allergic reactions, wounds, amputations etc.;
* unable to receive blood pressure measurements per cuff due to lymphedema, amputation, dyalisis shunt, wounds, etc.;
* pregnant women;
* breastfeeding women;
* upper arm circumference not within the cuff range (22-42 cm)
* unable or not willing to sign informed consent;
* significant mental or cognitive impairment

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-07-2024
Enrollment:	80
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO

Date:	18-04-2024
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	05-08-2024
Application type:	Amendment
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	ID
CCMO	NL85769.058.23