MMT-Corsano 287 CardioWatch

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26299

Source
NTR

Brief title
Corsano

Health condition

All patients presenting at CCN that are scheduled for a resting ECG qualify for participation

Sponsors and support

Primary sponsor: MMT Swiss Connect
Source(s) of monetary or material Support: MMT Swiss Connect

Intervention

Outcome measures

Primary outcome

The percentage of HR and RR-intervals detected by the smartwatch, matching with the resting ECG recording.

Secondary outcome

N.A.

Study description

Background summary

Patients will be recruited from the outpatient clinics of Cardiology Centers of the Netherlands (CCN). Eligible patients have been scheduled by their treating cardiologist for a resting ECG. Participants will wear a smartwatch, measuring pulse rate, while simultaneously having a 5 minute resting ECG recorded. In this study we will investigate the efficacy and safety of the smartwatch, intended to monitor pulse rate and RR-intervals, based on a comparison to the classical resting ECG recording. Raw data in XML-format from both smartwatch and ECG-recording will be compared on heart rate and RR-intervals.

The sample size calculation was done with PASS (version 15.0.2) for two-sided exact Clopper-Pearson 95% confidence intervals for one proportion (sensitivity). A sample size of 30'000 heart beats (thus 100 patients with approx. 300 heart beats each per 5 minutes) produces a two-sided 95% confidence interval with a width equal to 0.007 and a lower limit of the 95% confidence interval of 0.897 when the sample proportion is 0.900. It is expected that the width of the confidence interval will be slightly wider when a general estimating equation model (GEE) is used as analysis that takes into account that observations are correlated within subjects.

Study objective

The expected sensitivity of the CardioWatch 287 is 95%, as compared to the classical resting ECG recording. Sensitivity is defined as the percentage of HR and RR-intervals detected by the smartwatch, matching with the resting ECG recording.

Study design

Within this study a one-time baseline measurement will be conducted and there will be no follow-up.

When the patient is present at the outpatient clinic and scheduled for a resting ECG, the smartwatch will start the PPG-recording simultaneously with the ECG-recording. The two simultaneous recordings will be extracted and exported in XML-format and compared on the outcome as described above.

Intervention

N.A.

Contacts

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Sebastiaan Blok

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Scientific
Amsterdam University Medical Center, location AMC
Sebastiaan Blok

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Eligibility criteria

Inclusion criteria

Patients at CCN, scheduled for a resting ECG
Aged 18 years or above

Exclusion criteria

Under the age of 18
Subjects who are currently enrolled in another clinical investigation in which the intervention might compromise the safety of the subject's participation in this study.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-07-2020
Enrollment:	100
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	09-07-2020
Application type:	First submission

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
NTR-new	NL8866
Other	METC AMC : W20_285 # 20.321

Study results