Tina-quant Lp(a) RxDx Phase III Trial Sample Measurement

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Coronary artery disorders
Study type	Interventional

Summary

ID

NL-OMON51370

Source
ToetsingOnline

Brief title
Tina-quant Lp(a) RxDx Phase III Trial Sample Measurement

Condition

- Coronary artery disorders

Synonym
Cardiac, heart

Research involving
Human

Sponsors and support

Primary sponsor: Roche Diagnostics
Source(s) of monetary or material Support: Roche is sponsoring the performance study.

Intervention

Keyword: atherosclerotic, cardiac, lipoprotein

Outcome measures

Primary outcome

The objective of this study is to support the pharma partner*s Phase III trial using Tina-quant Lipoprotein (a) RxDx assay for subject selection and optional batch testing of follow-up samples. This study is carried out to evaluate the performance of Tina-quant Lipoprotein (a) RxDx assay in circumstances similar to the routine conditions of use.

The data obtained from this study will be used in the performance evaluation process and be part of the clinical evidence for the device. Data generated under this study in combination with the clinical outcomes of Phase III trial, if it reaches the safety and efficacy endpoint, will be used to validate the assay clinically and thus for registration of the product with regulatory authorities.

Secondary outcome

N/A

Study description

Background summary

Tina-quant Lp(a) RxDx is an in vitro quantitative test for the determination of lipoprotein (a) in human serum on cobas c systems. Tina-quant Lp(a) RxDx is indicated as an aid in the identification of patients with atherosclerotic cardiovascular disease and elevated lipoprotein (a) for treatment with the pharma partner*s candidate drug.

Study objective

The objective of this study is to support the pharma partner*s Phase III trial using Tina-quant Lipoprotein (a) RxDx assay for subject selection and optional batch testing of follow-up samples. This study is carried out to evaluate the performance of Tina-quant Lipoprotein (a) RxDx assay in circumstances similar to the routine conditions of use.
The data obtained from this study will be used in the performance evaluation process and be part of the clinical evidence for the device. Data generated under this study in combination with the clinical outcomes of Phase III trial, if it reaches the safety and efficacy endpoint, will be used to validate the assay clinically and thus for registration of the product with regulatory authorities.

Study design

This diagnostic study includes the following experimental parts:
1. Study Familiarization
Within-run precision In this part of the study, the site personnel should get acquainted with the system, reagents, and experimental design, WinCAEv and/or WebCAEv. The appropriate function of the instrument and the reagent handling are verified by performing a within-run precision experiment with controls supplied by RDS. If the experiment performed in the Study Familiarization does not meet the acceptance criteria, the root cause has to be found before the other study parts can start. The data of the Study Familiarization experiments are not used for evaluation of performance claims.
2. Initial Trial
LQ20
The Initial Trial has two parts. The first part of the Initial Trial is to determine site-specific intermediate precision and bias in control recovery (LQ20 experiment). Controls will be measured in 20 independent runs (the procedure can be done in approx. 10 days (with a maximum of 2 runs per day) or approx. 5 days (with a maximum of 4 runs per day). The intermediate precision and bias will be used to define site-specific QC criteria. This experiment may also be performed for a lot rollover or a new instrument setup over the course of the study.
Correlation sample panel (CSP) The second part of the Initial Trial is to assess laboratory bias using a correlation sample panel. Correlation sample panel covers the measuring range of Tina-quant Lipoprotein (a) RxDx assay. A method comparison analysis will be performed to compare the results of the measurement to the target values established by RDS to determine the bias. The site can only proceed to the Main Trial when the acceptance criteria are met.
3. Main Trial
Measurement of clinical samples During the Main Trial, clinical samples collected from the Phase III trial will be measured. The RDS CRA will perform data checks on validity of calibration and daily QC. Only after verification of

the validity of the Cal and QC measurements, the sample measurement data can be released for transfer to the database defined by the pharma partner.
Measurement of follow-up samples (optional) The pharma partner may collect clinical samples from enrolled participants after treatment with the investigational drug. If requested by the pharma partner, RDS will support the measurement of these follow-up samples. The same procedure will be followed as outlined in the Main Trial.

Intervention

The pharma partner's candidate drug will be compared to placebo. The placebo will look like the pharma partner's candidate drug but it will not contain active ingredients. A placebo has no medical effect but looks like the study drug. Receiving placebo is the same as not taking any Lp(a) lowering treatment. The pharma partner's candidate drug and placebo are both called study drug in this form.
The pharma partner's is being developed as an experimental drug and is not approved by any regulatory health agency (the Food and Drug Administration [FDA], Therapeutic Goods of Australia [TGA], or European Medicines Agency [EMA]).
The performance study IVD does not directly intervene with the subjects.

Study burden and risks

No direct risk associated with participating in the performance study to the subject.

Contacts

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Selecteer

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NL
Scientific
Selecteer

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NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

For diagnostic trial, samples to arrive frozen for testing. Samples must be serum samples.

Exclusion criteria

For diagnostic trial, inclusion criteria not fulfilled.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Diagnostic

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated):	30-05-2023
Enrollment:	450
Type:	Actual

Medical products/devices used

Generic name:	Tina-Quant LP(a) RxDx
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO Date:	10-05-2023
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	07-06-2023
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	18-10-2023
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	06-06-2024
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	21-11-2024
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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	NL82275.000.22