Performance of an omics-signature in the diagnosis and prognosis of endocrine and primary hypertension
A sub study of the ENSAT-HT Horizon 2020 project

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON42833

Source
ToetsingOnline

Brief title
ENSAT-HT

Condition

- Other condition

Synonym
High blood pressure

Health condition

Hypertensie

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Europese Unie

Intervention

Keyword: Endocrine hypertension, Omics-signature, Primary hypertension

Outcome measures

Primary outcome

The primary endpoint is the diagnostic performance (sensitivity, specificity, positive and negative predictive value and diagnostic odds ratios) of omics to diagnose EHBP.

Secondary outcome

The secondary endpoints are defined as following:

- Occurrence of major adverse cardiovascular events (MACE) within 12 months after V1 defined as: death, myocardial infarction (MI), percutaneous coronary intervention (PCI), coronary artery bypass grafting (CABG) or need for them, cerebrovascular accident (CVA), hospitalization for acute decompensated heart failure.

- Left ventricular (LV) hypertrophy, microalbuminuria, atrial fibrillation

- Quality of life and 'psychomics': , RAND36, (quality of life), EQ5D (quality of life), HADS (anxiety and depression), CFQ (cognitive functioning) and MOCA (cognitive functioning)

- costs (cost of evaluation, cost of misdiagnosis)

- BP level on ABPM/HBPM, number of drugs, Defined Daily Dosages (DDD)

(http://www.whocc.no/ddd/definition_and_general_considera/)

Study description

Background summary

Arterial hypertension is the most important cause of death in the world. At referral hypertension centers about 25% of patients have a single cause for hypertension, so-called secondary hypertension, mostly of endocrine, adrenal origin (primary aldosteronism, pheochromocytoma/ paraganglioma, Cushing's syndrome). This rate steps up to 50% in patients with drug resistant hypertension. Proper treatment of secondary hypertension improves prognosis considerably but depends on adequate diagnosis. Classically the diagnosis of such forms of hypertension rests on cumbersome biochemical and imaging procedures that may not completely take away uncertainty. Modern '-omics' techniques (genomics, metabolomics, proteomics of plasma and urine) may allow faster and better diagnosis. In addition, they may provide a basis for stratification of hypertensive patients that do not have a identifiable cause of hypertension, so-called primary hypertension. This stratification may help predicting response to antihypertensive drugs and determining prognosis and thus, help to establish personalized medicine in hypertension care.

Study objective

: The main objective of WP4 is to assess the validity and usefulness of omics signatures identified and validated in WPs 1, 2 and 3 for improved identification and risk stratification of patients with EHBP and stratification of patients with PHT.
The specific objectives of the WP are:
- To compare the diagnostic accuracy of omics-based signatures for identifying patients with EHBP compared with standard procedures.
- To determine the prognostic value of the omics signatures by assessing their relationship with outcome measures after one year follow-up, including BP, BP related target organ damage (TOD) and Quality of Life (QoL).
- To assess the potential usefulness of the omics signatures for stratification of patients with PHT.
- To relate the use of omics signatures to the social impact of hypertension, including QoL, degree of psychosocial burden, patients* lives and economic effects

Study design

Prospective observational multi-centre cohort study in which we will compare the diagnostic value of -omics signatures with currently used diagnostic

methods to detect adrenal forms of hypertension. The omics signatures will be identified from biobanks obtained in retrospective historical cohorts of more than 500 patients with confirmed adrenal hypertension by integrating high throughput genetics, genomics and metabolomics data with phenome annotations through bioinformatics modeling. Nested case-control studies of endocrine hypertension and primary hypertension will be used for follow-up.

Study burden and risks

In this study hypertensive patients will be diagnosed applying usual diagnostic algorithms . The only burden of participation is the sampling of extra blood and urine at the start of the diagnostic phase and at the end of the follow-up period and filling out Quality of Life (QoL) questionnaires.

Contacts

Public
Radboud Universitair Medisch Centrum

Geert-Grooteplein 10
Nijmegen 6525 GA
NL
Scientific
Radboud Universitair Medisch Centrum

Geert-Grooteplein 10
Nijmegen 6525 GA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Aged from 18 to 75 years old
- A signed and dated informed consent form
- A diagnosis of hypertension defined either as:
o Use of antihypertensive drug (s)
o Arterial hypertension: in untreated patients this must be confirmed by daytime ambulatory blood pressure monitoring (ABPM), or home blood pressure monitoring, with blood pressure higher or equal to 135 mmHg for systolic blood pressure and/or higher or equal to 85 mmHg for diastolic blood pressure. ;In order to be eligible to participate in the nested case control study, a subject must also meet the following criteria:
- A conformed diagnosis of PA, PPGL or CS for case patients and PHT (exclusion of secondary forms) for their matched counterparts

Exclusion criteria

potential subject who meets any of the following criteria will be excluded from participation in the prospective cohort is any of the following criteria will be present:
- Any severe comorbid conditions that, according to the attending physician, could decrease the life expectancy to less than 3 years
- Any active malignancy unrelated to adrenal disease or PPGL ;- Guardianship for incapacity;A potential control subject who meets any of the following criteria will be excluded from participation in the nested case controlled study in case of:
- Existence of any other forms of secondary hypertension such as renal artery stenosis, renal disease, Munchausen*s syndrome
- Drug-induced hypertension
- Documented non-adherence to medication

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2017
Enrollment:	400
Type:	Actual

Ethics review

Approved WMO Date:	29-06-2016
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL57215.091.16