Trial Description

Title

VIACORIND® In Daily Practice – Effectiveness and tolerability of VIACORIND® in hypertensive patients

Trial Acronym

VIACORIND®-IDP

URL of the trial

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Brief Summary in Lay Language

**Aim of this observational study is to gain information on the use of VIACORIND® in hypertensive patients under the conditions of daily practice in Germany.
Focus of the study is the change in the blood pressure, laboratory parameters and concomitant treatments as well as therapy adherence, quality of sleep and personal disease burden. Information on the general tolerability as well as specific adverse events will be collected.**

Brief Summary in Scientific Language

**Aim of this non-interventional study (NIS) is to gain information on the use of VIACORIND® in patients with essential hypertension in line with the marketing authorization under the conditions of daily practice in Germany.
Focus of the study is the change in the blood pressure (office, ABPM, home), laboratory parameters (total cholesterol, HDL, LDL, triglycerides, fasting glucose, HbA1c, urinary albumin, serum creatinine, serum sodium, serum potassium and serum uric acid) and concomitant treatments as well as therapy adherence, quality of sleep and personal disease burden. Information on the general tolerability as well as specific adverse events will be collected.**

Organizational Data

- DRKS-ID: **DRKS00015675**
- Date of Registration in DRKS: **2018/10/10**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **Pending/not yet approved**
- (leading) Ethics Committee Nr.: **18058 , Ethik-Kommission der Bayerischen Landesärztekammer**

Secondary IDs

Health condition or Problem studied

- ICD10: **I10.9 - [generalization I10: Essential (primary) hypertension]**

Interventions/Observational Groups

- Arm 1: **Adult outpatients with essential hypertension who are treated with VIACORIND® according to indication.**
  In general, all planned examinations within this NIS shall only be conducted if they are part of the usual diagnostic and therapeutic procedure of daily practice. No measures shall be taken, which exceed the normal medical routine.

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Treatment**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Duration of Observation: approx. 3 months
Documentation of data via standardized patient and physician questionnaires at 3 visits: baseline (V1, start of therapy), control examination (V2, approx. one month after V1) and final visit (V3, approx. 3 months after V1)

Following questions are to be analyzed:
1) Influence of the VIACORIND® therapy on office BP (Blood pressure), home BP and ambulatory blood pressure measurement (ABPM, documentation at every visit (V1-V3))
2) Influence of the VIACORIND® therapy on the laboratory parameters (total cholesterol, HDL, LDL, triglycerides, fasting glucose, HbA1c, urinary albumin,

serum creatinine, serum sodium, serum potassium and serum uric acid; documentation at V1 and V3)
3) Influence of the VIACORIND® therapy on the concomitant treatments, esp. on the cardiovascular treatments (documentation at visit V1, V2 and V3)
4) Evaluation of the pill burden and blood pressure self-measurement (frequency) prior to and during therapy with VIACORIND® (documentation at V1 and V3)
5) Influence of the VIACORIND® therapy on therapy adherence (documentation at V1 and V3)
6) Evaluation of quality of sleep and personal disease burden (documentation at V1 and V3)
7) Gathering of knowledge regarding general tolerability and specific adverse events and adverse drug reactions under VIACORIND® therapy (documentation at V2 and V3)
8) General assessment of the VIACORIND® therapy in patients with essential Hypertension (documentation at V3)

Secondary Outcome

no secondary endpoints defined

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- **deutschlandweit, [---]***

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2018/10/01**
- Target Sample Size: **2100**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

- the patient has at least 18 years of age
- the patient is treated with VIACORIND® in compliance with the summary of product characteristics
- only patients for whom a therapy with VIACORIND® is clinically necessary and has already been planned before study start
- the patient is informed about participating in this NIS and transfer of clinical data; his/her written informed consent is obtained

Exclusion criteria

• Patients under 18 years of age and incapable of giving their consent must not participate in this study
• Patients with contraindications according to the summary of prodcut characteristics must not participate in this study

Addresses

■ **Primary Sponsor**

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Sources of Monetary or Material Support

- **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

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Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

- Approval of ethics comm. (mandatory for transfer to Studybox) **Viacorind-IDP-Beobachtungsplan**

** This entry means the parameter is not applicable or has not been set.*
**** This entry means that data is not displayed due to insufficient data privacy clearing.*