Trial Description

Title

EVALUATION OF ANTIHYPERTENSIVE EFFECTS OF FREQUENT thermoneutral BATHS, A RANDOMIZED CONTROLLED TRIAL

Trial Acronym

ASCLEPIOS (ASSESSING CLINICAL EFFECTS OF PHYSIOLOGICAL IMMERSION IN HYPERTENSIVE SUBJECTS)

URL of the trial

[---]*

Brief Summary in Lay Language

Despite numerous treatment options, there are still many people whose high blood pressure is not treated sufficiently, either because of side effects, lack of efficacy or lack of acceptance of the drugs. Non-drug interventions (diet, exercise, weight reduction) are also proven to be efficient, but for various reasons often not sufficiently implemented, so there is need for additional therapies. BAthind in theraml baths is pleasant, leads to a significant short term reduction in blood pressure and has a high acceptance among the population and could be another complementary therapy. The long-term effects of thermal baths on blood pressure has been seldom studied. This trial will investigate, in which frequency thermal baths lead to a sustainable effect on blood pressure. Main outcome measures are early morning blood pressure and 24-hour blood pressure measurement before and after 4 and 24 weeks of therapy, other criteria are further blood pressure values, quality of life, relaxation, laboratory values, weight. Since some questions have not been clarified, eg the acceptance of frequent baths, whether there is sufficient interest ion this therapy, suitable measurement parameter, the expected decrease in blood pressure, this study is the pilot phase of a possibly following main study.

Brief Summary in Scientific Language

Baths in thermal neutral water are pleasant, lead to a significant acute reduction in blood pressure and have a high acceptance among the population and might be a complementary therapy to lower blood pressure. The long-term effects of baths on blood pressure are yet barely investigated. It should be investigated, in which frequency thermoneutral baths lead to to a sustainable antihypertensive effect. Primary outcome measures are early morning blood pressure and 24-hour blood pressure measurement before and after 4 and 24 weeks of therapy, secondary outcome measures are further blood pressure parameters, quality of life in the SF 12, relaxing in the PSQ, laboratory values, weight. The study is conducted as a single-center, randomized, three-arm controlled study. Since some questions have not been clarified, eg acceptance frequent baths, recruitment, appropriate measurement parameters, the expected reduction in blood pressure, this is the pilot phase of a following trial.

Organizational Data

- DRKS-ID: **DRKS00003980**
- Date of Registration in DRKS: **2012/07/10**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **111/12 , Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

Secondary IDs

Health condition or Problem studied

- ICD10: **I10.0 - [generalization I10: Essential (primary) hypertension]**

Interventions/Observational Groups

- Arm 1: **24 weeks 4 baths per week in thermo-neutral water for 60 minutes**
- Arm 2: **4 weeks 4 baths per week, 20 weeks 1 bath per week in thermo-neutral water for 60 minutes**
- Arm 3: **24 weeks non-drug antihypertensive action, corresponding to an information document (Deutsche Herzstiftungand at least 40 minutes daily relaxation exercises according to the specifications issued by a CD.**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Active control**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **No**

Primary Outcome

morning blood pressure and 24-hour-RR measurement (diastolic, systolic, and MAP) before treatment, after 4 weeks of therapy and after 24 weeks of therapy

Secondary Outcome

Other parameters of the 24-hour-RR measurement, additional RR measurements of the diary, weight, waist circumference
Number of responders (RR = reduction by more than 5 mmHg or reduction of medication antihypertensiven)
Additional laboratory parameters (BB, sodium, potassium, creatinine, CK, chol, CRP,
Aldosterone, renin, angiotensin, N-präANP, cortisol in hair), should provide clues to the mode of action of the baths. Blood is taken on scheduled dates.
Through questionnaires (SF36, PSQ, own questionnaire) to be detected in as much relaxation, stress reduction, quality of life or other subjective parameters can explain the effect.
In addition, detection of potential problems and acceptance of therapy baths and the control treatment.
Adverse events.
Influence of the frequency and duration of the baths.
Subgroups that benefit most from therapy (gender, age)

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **IBF Balneologie, Freiburg im Breisgau**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2012/07/23**
- Target Sample Size: **60**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

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

Additional Inclusion Criteria

Known Arterial Hypertension
• Blood pressure: systolic RR 140-180, 90-110 diastolic (hypertension grade 1 and 2), with and without antihypertensive drugs,
•> 18 years
• existence of a written consent of the patient
• sufficient knowledge of German for questionnaires, and being able to perform an ambulatory RR-measurement
• Willingness and ability to perform over 26 weeks 4 baths per week, or relaxation exercises,

Exclusion criteria

Participation in other interventional trials
• risk factors, organ damage, DM, metabolic syndrome are no exclusion criteria per se, but only
• heart failure class III and IV (clinical, echocardiographic in doubt and / or verified by BNP)
• Grade IV PAD (clinically confirmed if necessary Doppler or duplex
• renal failure, creatinine> 1.5 mg / dl
• acute infection, fever
• Unstable AP
• or very severe disease
• change in antihypertensive medication last 4 weeks
• Secondary hypertension indication for treatment with antihypertensive drugs other than (further clarification necessary only for clear indications, such as hypokalemia, flushing, etc.)
• The need for a change of antihypertensive medication in the next 4 weeks
• reasons to exclude the public bath (open wounds or similar)
• Regular baths (> 1 per week) in past 2 months
• Pregnancy

Addresses

■ **Primary Sponsor**

Universitätsklinikum Freiburg
Hugstetter Strasse 49
79095 Freiburg
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **www.uniklinik-freiburg.de**

■ **Contact for Scientific Queries**

IBF Balneologie am IUK, Uniklinik Freiburg
Mr. Dr.med Johannes Naumann
Herbert-Hellmann-allee 12
79189 Bad Krozingen

Contact for Scientific Queries

IBF Balneologie am IUK, Uniklinik Freiburg
Mr. Dr.med Johannes Naumann
Herbert-Hellmann-allee 12
79189 Bad Krozingen
Germany

Telephone: **07633-4008-501**
Fax: **07633-4008-22**
E-mail: **johannes.naumann at uniklinik-freiburg.de**
URL: **http://www.uniklinik-freiburg.de/iuk/live/balneologie.html**

- **Contact for Public Queries**

IBF Balneologie
der Uniklinik Freiburg
Mr. Dr. med. Johannes Naumann
Herbert-Hellmann-Allee 12
79189 Bad Krozingen
Germany

Telephone: **0049-7633-4008-502**
Fax: **0049-7633-4008-22**
E-mail: **johannes.naumann at uniklinik-freiburg.de**
URL: **www.uniklinik-freiburg.de**

Sources of Monetary or Material Support

- **Institutional budget, no external funding (budget of sponsor/PI)**

Universitätsklinikum Freiburg
Hugstetter Strasse 49
79095 Freiburg
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **www.uniklinik-freiburg.de**

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2013/10/08**

Trial Publications, Results and other documents

** 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.*