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Low-dose radon hyperthermia therapy in atopic dermatitis

Submission date
24/06/2021

Recruitment status
No longer recruiting

Registration date
29/06/2021

Overall study status
Completed

Last Edited
27/08/2024

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Background and study aims
Atopic dermatitis (AD) is an inflammatory skin disease, mainly characterized by pruritus, skin dryness, and eczema. For some patients, conventional therapy methods are insufficient. These patients might benefit from Low-dose Radon Hyperthermia (LDRnHT) therapy. This is a well-recognized treatment method for inflammatory diseases in various compartments of the human body. Clinical studies demonstrated that LDRnHT- therapy can reduce pain, enhance functionality and positively shift crucial blood parameters. Many positive single reports from AD patients support this theory, but there are no clinical studies so far. The purpose of this pilot study is to evaluate whether AD patients can evidently benefit from LDRnHT.

Who can participate?
Patients aged 18 -70 years with chronic, moderate to severe AD

What does the study involve?
All study participants have to pass an initial examination (T0) at the Department of Dermatology and Allergology at the University Hospital Salzburg, Austria. Patients enrolled are randomised into a control and an intervention group. Participants attend a two-week cure stay in Bad Gastein. The intervention group receives eight sessions of LDRnHT in the Gastein Healing Gallery (average radon activity ≈44 kBq/m3; ambient temperature 37-41.5° C; air humidity ≥ 70%). The control group receives sauna treatments with the same ambient temperature and humidity but without radon. Short term modifications of skin condition and specific blood parameters are assessed, as well as questionnaires for skin condition and quality of life (Qol), comparing the initial situation (T0) to immediate post-radon-therapy (T1).
Long-term effects are documented in follow-up examinations at three, six and nine months after T1 (T2/T3/T4, respectively). At every examination, skin condition is assessed by a dermatologist using the SCORing Atopic Dermatitis rating tool, and blood samples and questionnaires are collected. Patients are asked to fill out the Patient Oriented SCORAD questionnaire using a computer or smartphone application, and the SKINDEX-29 tool to measure of the effect of the skin disease on quality of life. The EQ-5D-5L and VAS questionnaires are used to assess Quality of Life (Qol). At T0 and T2. If the condition of a participant becomes worse, the dermatologist is authorized to assign a different therapy and end a patient’s participation in the study.
In this pilot study, molecular parameters shall be investigated which reflect the therapeutic

effects of LDRnHT in AD patients. The results from this pilot study shall build a basis for the development of further hypotheses and larger studies investigating LDRnHT as a therapy option for AD.

What are the possible benefits and risks of participating?
Patients receive a cost-free cure stay in Bad Gastein. Improvement of skin condition might be achieved through LDRnHT.
Possible worsening of skin condition might occur due to elevated air humidity and temperature (ambient temperature 37-41.5°C; air humidity ≥ 70%) during treatments.

Where is the study run from?
The study is run from the Gastein Research Institute (Paracelsus Medical University in Salzburg) which is part of the Center for Physiology, Pathophysiology and Biophysics (Salzburg and Nuremberg, Austria and Germany), in cooperation with the Gastein Healing Gallery in Böckstein, Austria.

When is the study starting and how long is it expected to run for?
August 2016 to December 2020

Who is funding the study?
Cure stays and treatment funded by:
Gasteiner Kur-, Reha und Heilstollen Betriebsges.m.b.H. (Austria)
Other funding:
Gastein Research Institute, Center for Physiology, Pathophysiology and Biophysics, Salzburg and Nuremberg - Salzburg, Paracelsus Medical University Salzburg (Austria)
Gemeinnützige Salzburger Landeskliniken Betriebsgesellschaft mbH (Austria)

Who is the main contact?
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Contact information

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
E2126

Study information

Scientific Title
Study for the effectivity of low-dose radon hyperthermia therapy in the Gastein healing gallery on atopic dermatitis

Study objectives
This pilot study outcome shall provide information for further generation of hypotheses

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 25/01/2017, Ethikkommission für das Bundesland Salzburg (Sebastian-Stief-Gasse 2 5020 Salzburg, Austria), +43-(0)662-8042-2375, ethikkommission@salzburg.gv.at), ref: E.-Nr. 2126

Study design
Single-centre interventional open randomized explorative prognostic longitudinal pilot study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Effectivity of low-dose radon hyperthermia therapy on atopic dermatitis

Interventions
Patients with Atopic Dermatitis (AD) are recruited via the department of dermatology of the Salzburger Landeskliniken (Prim. Dr. Johann Bauer, SALK).

Patients are randomised to control (sauna treatment) and interventional groups (Low-dose Radon Hyperthermia Therapy (LDRnHT) in the Gastein Healing Gallery).

The randomisation process was carried out, regardless of any specific patient characteristics, via permuted block randomisation (block sizes: 7, 6, and 4).

Blood samples, questionnaires and survey of drug consumption were collected for timepoints before, directly after cure stay and three, six, and nine months after end of the cure stay.

Intervention Type
Procedure/Surgery

Primary outcome measure
SCORAD (SCORing Atopic Dermatitis) questionnaire for specific assessment of skin condition in AD at before, directly after cure stay and 3, 6, and 9 months after the end of the cure stay.

Secondary outcome measures
Measured before, directly after cure stay, and three, six, and nine months after the end of the cure stay:
1. Quality of life (EQ-5D-5L)
2. Skin condition (SKINDEX-29)
3. Analysis of blood samples (MDC/CCL22, CTACK/CCL27, TARC/CCL17, IgE, IL-4, IL-13)

Overall study start date
16/08/2016

Completion date
08/12/2020

Eligibility

Key inclusion criteria
1. Atopic Dermatitis, from chronic moderate to severe disease state. (mild: SCORAD <25, moderate SCORAD 25-50, severe SCORAD >50)
2. Patient SCORAD value must be between 25 and 50 for inclusion
3. AD must be diagnosed and verified by a dermatologist
4. Age range 18 - 70 years

5. Signed Informed Consent must be obtained from each patient
6. Patients must be able to fill out a questionnaire by themselves

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
70 Years

Sex
Both

Target number of participants
32

Total final enrolment
34

Key exclusion criteria
1. Pregnancy or breast feeding period
2. Incompatibility of patients to treatment methods
3. Erosions, ulcers
4. Viral or bacterial superinfections
5. Severe internal diseases
6. Consumption of potential photosensitizers
7. Concomitant or past malignant skin tumors
8. Radon therapy or similar radiation (UV/light) treatment within the past year
9. Consumption of oral immunosuppressive drugs (within 6 months before entering the study)
10. Claustrophobia

Date of first enrolment
25/01/2017

Date of final enrolment
06/07/2020

Locations

Countries of recruitment
Austria

Germany

Study participating centre
Gasteiner Kur-, Reha- und Heilstollen Betriebsges.m.b.H.
Heilstollenstraße 19
Böckstein
Bad Gastein
Austria
5645

Study participating centre
Gastein Research Institute, Center for Physiology, Pathophysiology and Biophysics, Salzburg and Nuremberg - Salzburg, Paracelsus Medical University Salzburg
Strubergasse 22
Salzburg
Austria
5020

Study participating centre
Gemeinnützige Salzburger Landeskliniken Betriebsgesellschaft mbH
Müllner Hauptstraße 48
Salzburg
Austria
5020

Sponsor information

Organisation
Salzburger Landeskliniken

Sponsor details
St. Veiter Straße 46
St. Veit im Pongau
Austria
5621
+43 (0)5 7255 - 46000
aed.lk-stveit@salk.at

Sponsor type
Hospital/treatment centre

Website
https://salk.at/Landesklinik_St_Veit.html

ROR

https://ror.org/0500kmp11

Organisation
Salzburger Landeskliniken

Sponsor details
Müllner Hauptstraße 48
Salzburg
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5020
+43 (0)5 7255-0
joh.bauer@salk.at

Sponsor type
Hospital/treatment centre

Website
https://www.salk.at/

ROR
https://ror.org/0500kmp11

Organisation
Paracelsus Medizinische Privatuniversität

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Sponsor type
University/education

Website
https://www.pmu.ac.at/

ROR
https://ror.org/022zhm372

Funder(s)

Funder type
University/education

Funder Name
Paracelsus Medizinische Privatuniversität

Alternative Name(s)
Paracelsus Medical University, PMU

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Austria

Funder Name
Gasteiner Kur-, Reha und Heilstollen Betriebsges.m.b.H.

Funder Name
Gemeinnützige Salzburger Landeskliniken Betriebsgesellschaft mbH

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
30/11/2024

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version v4	12/06/2019	08/07/2021	No	Yes

Protocol file	In German	31/12/2017	10/08/2022	No	No