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Radon indication registry for the assessment of pain reduction, increase of quality of life and improvement in body functionality throughout low-dose radon hyperthermia therapy

Submission date
14/09/2021

Recruitment status
Recruiting

Registration date
11/10/2021

Overall study status
Ongoing

Last Edited
01/08/2023

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Radon is a noble gas that naturally occurs in thermal waters and thermal galleries in the Gastein Valley. Several studies have investigated the effects of low-dose radon hyperthermia therapy, either in form of speleotherapy (Gastein Healing Gallery) or balneotherapy (Radon Thermal Baths), on patients suffering from inflammatory and non-inflammatory degenerative diseases of the musculoskeletal system. Still, there is a lack of long-term records of larger patient cohorts documenting the impact of radon therapy in detail.
The radon registry study shall serve as such a long-term record. The aim of this study is to systematically assess field reports of spa physicians on radon therapy, and to include these findings purposefully into current methods in spa medicine. In the radon registry study, seven conditions are assessed (see 'Who can participate?' section below).
In most studies, a first positive response to radon therapy occurs 2 to 3 months after the intervention, when compared to the control group. Therefore, a systematic long-term assessment of therapy success might show the effects of radon therapy on different conditions. The establishment of a radon registry is highly meaningful, as many patients have already benefited from radon therapy during their cure stays in the past.
Therapy success, however, has not yet been investigated in a broader range, neither specific for any indication nor for its duration. In addition to patients filling out questionnaires, the study will assess which therapies the patients received and for how long, and the cumulative radon dose will be deduced. Consequently, it might be possible to draw relationships between therapy success and optimized treatment concepts, including radon therapy.

Who can participate?
Patients aged over 25 and under 75 years with ankylosing spondylitis, rheumatoid arthritis, back pain, osteoarthritis of the hip and knee, fibromyalgia syndrome, or psoriatic arthritis, who have not received radon therapy within the last year

What does the study involve?
During their cure stay, patients receive radon therapy as prescribed by the responsible clinician: 10 radon baths within 3-5 weeks and 8-12 sessions in the Gastein Healing Gallery within 3-5 weeks. Patients are asked to fill in questionnaires measuring pain, quality of life and indication-specific questions before the cure stay, directly after the cure stay, and 3, 6 and 9 months after.

What are the possible benefits and risks of participating?
There are no direct benefits for the participants. This study aims to improve radon therapy for the future. A possible risk might be leakage of sensitive patient data, which is prevented by using pseudonyms and limited access to the data.

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, Kurzentrum Bad Hofgastein in Bad Hofgastein, Austria, Gesundheitszentrum Bärenhof in Bad Gastein, Austria, and Stiftung Kurtherme Badehospiz in Bad Gastein, Austria.

When is the study starting and how long is it expected to run for?
August 2015 to December 2041

Who is funding the study?
1. Kurzentrum Bad Hofgastein (Austria)
2. Stiftung Kurtherme Badehospiz (Austria)
3. Gasteiner Kur-, Reha und Heilstollen Betriebsges.m.b.H. (Austria)
4. Gesundheitszentrum Bärenhof Bad Gastein (Austria)

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
E-1966

Study information

Scientific Title
Radon Indication Registry - a multi-centre, hypothesis-generating, explorative, uncontrolled, non-interventional, open registry study for the assessment of pain reduction, increase of quality of life and improvement in functionality throughout low-dose radon hyperthermia therapy

Acronym
RadReg

Study objectives
The aim of the study is to systematically assess field reports of spa physicians on radon therapy, and to include these findings purposefully into current methods in spa medicine. In the radon registry study, seven indications are assessed (see 'Study Information - Condition'). Subsequently, evidence-based knowledge shall be generated and made accessible to medicine and science.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 09/12/2015, Ethikkommission für das Bundesland Salzburg (Sebastian-Stief-Gasse 2 5020 Salzburg, Austria), +43-(0)662-8042-2375, ethikkommission@salzburg.gv.at), ref: E.-Nr. 1966

Study design
Multi-centre non-interventional open uncontrolled explorative hypothesis-generating registry study

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Non-inflammatory, degenerative diseases of the musculoskeletal system: ankylosing spondylitis, rheumatoid arthritis, back pain, osteoarthritis in hip and knee, fibromyalgia syndrome, psoriatic arthritis

Interventions
There are no direct interventions in this registry study. Patients undergo a 2 to 3-week cure stay in the Gastein valley. At the participating medical centers (Gasteiner Heilstollen, Kurzentrum Bad Hofgastein, Gesundheitszentrum Bärenhof, Stiftung Kurtherme Badehospiz), patients fill out questionnaires (quality of life, pain scores, indication-specific questionnaires) at their first clinical assessment (T0) and when they leave (T1). Until 9 months follow-up, in a 3-month rhythm (T2, T3, T4), patients get sent the follow-up questionnaires. Moreover, therapies received during the cure stays shall be assessed to create an overall picture of therapy success for each patient.

Intervention Type
Behavioural

Primary outcome(s)
Measured at T0 (before cure stay), T1 (discharge), T2 (3 months), T3 (6 months), T4 (9 months):
1. Pain scores for rest and movement measured using NRS (numeric rating scale)
2. Quality of life measured using EQ-5D-5L
3. Indication-specific:
3.1. OA: severity of osteoarthritis of the hip and knee measured using the Lequesne index
3.2. RA: RA disease activity and course measured using the Rheumatoid Arthritis Disease Activity Index (RADAI-5)
3.3. Ankylosing spondylitis: degree of functional limitation measured using the Bath Ankylosing Spondylitis Functional Index (BASFI), disease activity measured using the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI)
3.5. Back pain: back pain-related functional limitations measured using the Funktionsfragebogen Hannover Rücken (FFb-H-R)
3.6. Fibromyalgia syndrome: fibromyalgia (FM) patient status and progress assessed using the Fibromyalgia Impact Questionnaire (FIQ)
3.7. Psoriatic arthritis: the impact of PsA for the patient assessed using the PsAID 12

Key secondary outcome(s))
Reduction of drug intake (e.g. NSAR) measured using the responsible clinician's protocols for each patient before and after cure stay (T0 vs T1)

Completion date
01/12/2041

Eligibility

Key inclusion criteria
1. Age >25, <75 years
2. No radon therapy within the last year
3. BMI >18, <34 kg/m²

4. Being diagnosed one of the six possible indications (ankylosing spondylitis, rheumatoid arthritis, back pain, osteoarthritis in hip and knee, fibromyalgia syndrome, psoriasis arthritis)
5. Being able to attend any form of radon therapy performed in the Gastein Valley

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
25 years

Upper age limit
75 years

Sex
All

Key exclusion criteria
1. Severe cardiovascular disease/arrhythmia
2. Severe kidney dysfunction/inflammatory kidney participation in the context of an autoimmune disease
3. Acute infections
4. Highly acute attack in chronic polyarthritis
5. Hyperthyroidism
6. Malignancy patients: last accomplished chemotherapy or immune therapy has taken place <1 year ago
7. Pregnancy
8. Alcohol and/or drug abuse
9. Lacking language skills
10. Incapability of filling out a questionnaire

Date of first enrolment
09/12/2015

Date of final enrolment
01/01/2040

Locations

Countries of recruitment
Austria

Germany

Study participating centre
Kurzentrum Bad Hofgastein
Senator-Wilhelm Wilfing-Platz 1
Bad Hofgastein
Austria
5630

Study participating centre
Stiftung Kurtherme Badehospiz
Badbergstraße 1
Bad Gastein
Austria
5640

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

Study participating centre
Gesundheitszentrum Bärenhof Bad Gastein
Pyrkershöhenstraße 11
Bad Gastein
Austria
5640

Sponsor information

Organisation
Gastein Research Institute

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Kurzentrum Bad Hofgastein

Funder Name
Stiftung Kurtherme Badehospiz

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

Funder Name
Gesundheitszentrum Bärenhof Bad Gastein

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Interim results article	Results from ankylosing spondylitis patients	03/08/2022	11/10/2022	Yes	No
Interim results article	Pain symptons in patients with rheumatic musculoskeletal diseases	08/06/2023	01/08/2023	Yes	No